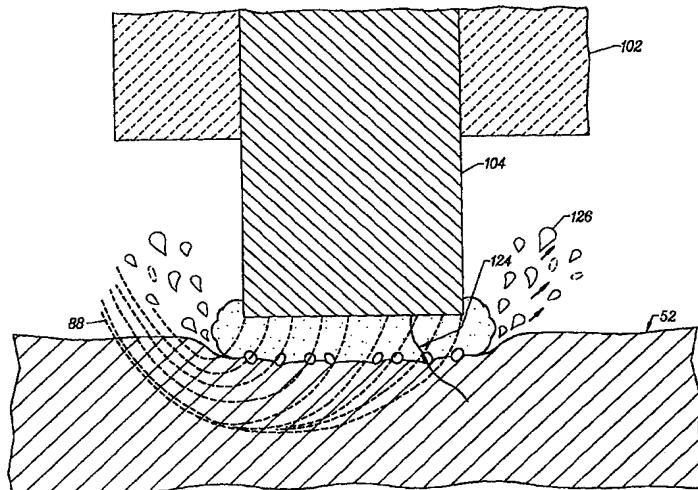




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(54) Title: SYSTEMS AND METHODS FOR ELECTROSURGICAL ABLATION OF Viable BODY STRUCTURES



## (57) Abstract

The present invention provides systems, and methods for removing tumors, lesions or other undesirable body structures while minimizing the spread of viable cells from the tumor or lesion. An electro-surgical instrument (102), such as a probe or catheter, is positioned in close proximity to a viable body structure so that one or more electrode terminal (104) are brought into at least partial contact or close proximity with target tissue on the body structure. High frequency voltage is then applied between the electrode terminal (104) and one or more return electrodes to volumetrically remove at least a portion of the tissue cells through the disintegration of organic molecules into non-viable atoms, and molecules. The solid tissue cells are converted into non-condensable gases that are no longer intact or viable, and thus, not capable of spreading the viral or bacterial particles from the body structure.

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**SYSTEMS AND METHODS FOR ELECTROSURGICAL  
ABLATION OF VIABLE BODY STRUCTURES****RELATED APPLICATIONS**

The present invention is a continuation-in-part of U.S. Patent Application  
10 08/795,686, filed February 5, 1997 (Attorney Docket No. 16230-000740), which is a  
divisional of U.S. Patent No. 5,697,882, filed November 22, 1995, the complete  
disclosures of which are incorporated herein by reference for all purposes. The invention  
is also a continuation-in-part of U.S. Patent Application Serial No. 08/990,374, filed on  
December 15, 1997 (Attorney Docket No. E-3), which is a continuation-in-part of U.S.  
15 Patent Application No. 08/485,219, filed on June 7, 1995 now U.S. Pat. No. 5,697,281  
(Attorney Docket 16238-0006000), which is a continuation-in-part of PCT International  
Application, U.S. National Phase Serial No. PCT/US94/05168, filed on May 10, 1994,  
now U.S. Patent No. 5,697,909, (Attorney Docket 16238-000440), which is a  
continuation-in-part of application Serial No. 08/059,681, filed on May 10, 1993  
20 (Attorney Docket 16238-000420), the complete disclosures of which are incorporated  
herein by reference for all purposes.

The present invention is also related to commonly assigned co-pending U.S.  
Patent Application Nos. 09/058,571, 08/874,173, and 09/002,315, filed on April 10,  
1998, June 13, 1997, and January 2, 1998, respectively (Attorney Docket Nos. CB-2,  
25 16238-005600 and C-9, respectively) and U.S. Patent Application No. 09/054,323, filed  
on April 2, 1998 (Attorney Docket No. E-5), U.S. Patent Application No. 09/010,382,  
filed January 21, 1998 (Attorney Docket A-6), and U.S. Patent Application No.  
09/032,375, filed February 27, 1998 (Attorney Docket No. CB-3), U.S. Patent  
Application Nos. 08/977,845, filed on November 25, 1997 (Attorney Docket No. D-2),  
30 08/942,580, filed on October 2, 1997 (Attorney Docket No. 16238-001300), 09/026,851,  
filed February 20, 1998 (Attorney Docket No. S-2), U.S. Application No. 08/753,227,  
filed on November 22, 1996 (Docket 16238-002200), U.S. Application No. 08/687792,  
filed on July 18, 1996 (Docket No. 16238-001600), the complete disclosures of which are  
incorporated herein by reference for all purposes.

## BACKGROUND OF THE INVENTION

The present invention relates generally to the field of electrosurgery, and 5 more particularly to surgical devices and methods which employ high frequency electrical energy to remove viable body structures, such as benign and cancerous tumors, congenital warts, surface lesions, infectious tissue and the like.

Many surgical procedures, open and endoscopic, involve the treatment and/or removal of tumors that have developed and grow on the surface of tissue or organs, 10 such as cancer on the skin, eye, colon, bladder, cervix, brain, uterus and the like.

Unfortunately, conventional techniques for removing such tumors generally result in the production of smoke in the surgical setting, termed an electrosurgical or laser plume, which can spread intact, viable bacterial or viral particles from the tumor or lesion to the surgical team or to other portions of the patient's body. This potential spread of viable 15 cells or particles has resulted in increased concerns over the proliferation of certain debilitating and fatal diseases, such as hepatitis, herpes, HIV and papillomavirus.

In the past several years, powered instrumentation, such as microdebrider devices and lasers, has been used to treat tissue in various procedures, such as removing 20 polyps or other swollen tissue in functional endoscopic sinus surgery. Microdebriders are disposable motorized cutters having a rotating shaft with a serrated distal tip for cutting and resecting tissue. The handle of the microdebrider is typically hollow, and it accommodates a small vacuum, which serves to aspirate debris. In this procedure, the distal tip of the shaft is delivered to the target site, and an external motor rotates the shaft 25 and the serrated tip, allowing the tip to cut tissue at the target site, such as sinus tissue, spinal tissue, or the like.

While microdebriders and other powered surgical instruments have been promising for some applications, they are not appropriate tools for removing bacterial or viral tumors from the body. For one thing, these devices produce smoke particles small enough to be considered breathable particles, yet too small to be effectively blocked by 30 standard surgical masks. Thus, the viral and bacterial particles can be spread to the surgical staff and to other parts of the patient's body. Moreover, these power surgical instruments are not very precise, and it is often difficult to differentiate between the target tumor tissue, and other neighboring body structures, such as cartilage, bone or nerves. In

particular, many tumors, such as those in the head and neck (e.g., the brain), are located closely adjacent to nerves. Nerve injury can lead to muscle paralysis, pain, exaggerated reflexes, loss of bladder control, impaired cough reflexes, spasticity and other conditions. Thus, the surgeon must be extremely careful to avoid damaging the nerves that extend 5 through the target site.

Lasers were initially considered ideal for many surgical procedures because lasers ablate or vaporize tissue with heat, which also acts to cauterize and seal the small blood vessels in the tissue. Unfortunately, lasers are both expensive and somewhat tedious to use in these procedures. Another disadvantage with lasers is the difficulty in 10 judging the depth of tissue ablation. Since the surgeon generally points and shoots the laser without contacting the tissue, he or she does not receive any tactile feedback to judge how deeply the laser is cutting. Because healthy tissue, cartilage, bone and/or nerves often lie within close proximity of the target tissue, it is essential to maintain a minimum depth of tissue damage, which cannot always be ensured with a laser. Perhaps most importantly, 15 the laser plume formed after each pulse may spread viable cells from the tumor or lesion that is being removed by the pulse of energy. Numerous studies have confirmed that viable cells, such as papillomavirus, HIV, cancer cells, and the like, are spread to other portions of the patient's body during these tumor removal procedures.

Recently, RF energy has been used to remove or otherwise treat tissue in 20 open and endoscopic procedures since they generally reduce patient bleeding associated with tissue cutting operations and improve the surgeon's visibility. These electrosurgical devices and procedures, however, suffer from a number of disadvantages. For example, conventional electrosurgical cutting devices typically operate by creating a voltage difference between the active electrode and the target tissue, causing an electrical arc to 25 form across the physical gap between the electrode and tissue. At the point of contact of the electric arcs with tissue, rapid tissue heating occurs due to high current density between the electrode and tissue. This high current density causes cellular fluids to rapidly vaporize into steam, thereby producing a "cutting effect" along the pathway of localized tissue heating. This cutting effect generally results in the production of smoke, or an 30 electrosurgical plume, which can spread bacterial or viral particles from the tissue to the surgical team or to other portions of the patient's body. In addition, the tissue is parted along the pathway of evaporated cellular fluid, inducing undesirable collateral tissue damage in regions surrounding the target tissue site.

## SUMMARY OF THE INVENTION

The present invention provides systems, apparatus and methods for 5 selectively applying electrical energy to tissue structures in or on a patient's body. The present invention is particularly useful for removing tumors, lesions, infectious tissue or other undesirable body structures while minimizing the spread of viable cells from the tumor or lesion.

Methods of the present invention comprise positioning an electrosurgical 10 instrument, such as a probe or catheter, in close proximity to a viable body structure (e.g., infectious tissue or cancerous or pre-cancerous tissue) so that one or more electrode terminal(s) are brought into at least partial contact or close proximity with target tissue on the body structure. High frequency voltage is then applied between the electrode terminal(s) and one or more return electrode(s) to volumetrically remove at least a portion 15 of the tissue cells in the body structure through the dissociation or disintegration of organic molecules into non-viable atoms and molecules. Specifically, the present invention converts the solid tissue cells into non-condensable gases that are no longer intact or viable, and thus, not capable of spreading viral or bacterial particles from the body structure.

In a preferred embodiment, an electrically conducting fluid is provided 20 between the electrode terminal(s) and one or more return electrode(s) positioned proximal to the electrode terminal(s) to provide a current flow path from the electrode terminal(s) to the return electrode(s). The current flow path may be generated by directing an electrically conducting fluid along a fluid path past the return electrode and to the target site, or by locating a viscous electrically conducting fluid, such as a gel, at the target site, and 25 submersing the electrode terminal(s) and the return electrode(s) within the conductive gel. In both embodiments, high frequency voltage is applied between the electrode terminal(s) and one or more return electrode(s) to volumetrically remove or ablate at least a portion of the tissue cells within the body structure. The high frequency voltage is preferably selected to effect controlled removal of these tissue cells while minimizing substantial 30 tissue necrosis to surrounding or underlying tissue.

The body structures are typically removed by molecular dissociation or disintegration processes. In these embodiments, the high frequency voltage applied to the electrode terminal(s) is sufficient to vaporize an electrically conductive fluid (e.g., gel or

saline) between the electrode terminal(s) and the tissue. Within the vaporized fluid, a ionized plasma is formed and charged particles (e.g., electrons) are accelerated towards the tissue to cause the molecular breakdown or disintegration of several cell layers of the tissue. This molecular dissociation is accompanied by the volumetric removal of the tissue.

5 The short range of the accelerated charged particles within the plasma layer confines the molecular dissociation process to the surface layer to minimize damage and necrosis to the underlying tissue. This process can be precisely controlled to effect the volumetric removal of tissue as thin as 10 to 150 microns with minimal heating of, or damage to, surrounding or underlying tissue structures. The small depths of collateral tissue damage

10 provided by the present invention allows the surgeon to remove tissue without causing collateral damage to adjacent or underlying body structure, such as nerve fibers, or other non-target tissue. Moreover, the tissue cells are broken down into non-condensable gases, such as hydrogen, oxygen, oxides of carbon and nitrogen compounds. These gases are typically not viable tissue cells, and therefore, do not spread viral or bacterial particles. A

15 more complete description of this phenomena is described in commonly assigned U.S. Patent No. 5,683,366, the complete disclosure of which is incorporated herein by reference

In a specific configuration, the present invention also provides systems and methods for distinguishing between cancerous or pre-cancerous tissue and normal tissue.

20 In one embodiment, the electrical properties of the tissue at the tip of the probe are measured with one or more electrode terminal(s). These electrical properties may include electrical conductivity at one, several or a range of frequencies (e.g., in the range from 1 kHz to 100 MHz), dielectric constant, capacitance or combinations of these. In this embodiment, an audible signal may be produced when the sensing electrode(s) at the tip of

25 the probe detects cancerous or pre-cancerous tissue, or direct feedback control can be provided to only supply power to the electrode terminal(s) either individually or to the complete array of electrodes, if and when the tissue encountered at the tip or working end of the probe is normal tissue based on the measured electrical properties.

In an exemplary embodiment, the power to the electrode terminals will shut down or turn off when the electrical impedance is above or below a threshold level. When this threshold level is set to the impedance of the cancerous or pre-cancerous tissue, for example, the electrode terminals will shut off whenever they come in contact with, or in close proximity to, normal tissue. Meanwhile, the other electrode terminals, which are in

contact with or in close proximity to cancerous or pre-cancerous tissue, will continue to conduct electric current to the return electrode. This selective ablation or removal of cancerous tissue in combination with the generally precise tissue removal capability of the present invention allows the surgeon to precisely remove cancerous tissue without 5 significantly damaging underlying and surrounding normal tissue, or other body structures, such as nerves.

Systems according to the present invention generally include an electrosurgical instrument having a shaft with proximal and distal ends, one or more electrode terminal(s) at the distal end of the shaft and one or more return electrode(s). 10 The system further includes a high frequency power supply for applying a high frequency voltage difference between the electrode terminal(s) and the return electrode(s). The voltage difference is sufficient to volumetrically remove at least a portion of the tissue cells through the disintegration of organic molecules into non-viable atoms and molecules.

The system may further include a fluid delivery element for delivering 15 electrically conducting fluid to the electrode terminal(s) and the target site. The fluid delivery element may be located on the instrument, e.g., a fluid lumen or tube, or it may be part of a separate instrument. Alternatively, an electrically conducting gel or spray, such as a saline electrolyte or other conductive gel, may be applied to the target site (e.g., directly on the valve). In this embodiment, the apparatus may not have a fluid delivery 20 element. In both embodiments, the electrically conducting fluid will preferably generate a current flow path between the electrode terminal(s) and the return electrode(s). In an exemplary embodiment, a return electrode is located on the instrument and spaced a sufficient distance from the electrode terminal(s) to substantially avoid or minimize current shorting therebetween and to shield the return electrode from tissue at the target site.

25 In a specific configuration, the electrosurgical instrument will include an electrically insulating electrode support member, preferably an inorganic support material (e.g., ceramic, glass, glass/ceramic, etc.) having a tissue treatment surface at the distal end of the instrument shaft. One or more electrode terminal(s) are coupled to, or integral with, the electrode support member such that the electrode terminal(s) are spaced from the return electrode. In one embodiment, the instrument includes an electrode array having a plurality of electrically isolated electrode terminals embedded into the electrode support member such that the electrode terminals extend about 0.0 mm to about 10 mm distally 30 from the tissue treatment surface of the electrode support member. In this embodiment,

the probe will further include one or more lumens for delivering electrically conductive fluid and/or aspirating the target site to one or more openings around the tissue treatment surface of the electrode support member. In an exemplary embodiment, the lumen will extend through a fluid tube exterior to the probe shaft that ends proximal to the return electrode.

### BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of an electrosurgical system incorporating a power supply and an electrosurgical probe for tissue ablation, resection, incision, contraction and for vessel hemostasis according to the present invention.

Fig. 2 is a side view of an electrosurgical probe according to the present invention.

Fig. 3 is an end view of the probe of Fig. 2.

Fig. 4 is a cross sectional view of the electrosurgical probe of Fig. 1.

Fig. 5 is an exploded view of a proximal portion of the electrosurgical probe.

Fig. 6 is a perspective view of an alternative electrosurgical probe incorporating an inner fluid lumen.

Figs. 7A-7C are cross-sectional views of the distal portions of three different embodiments of an electrosurgical probe according to the present invention.

Fig. 8 is a cross-sectional view of the distal tip of the electrosurgical probe, illustrating electric field lines between the active and return electrodes;

Fig. 9 is an enlarged cross-sectional view of the distal tip of the probe of Fig. 15, illustrating a vapor layer formed between the active electrodes and the target tissue;

Fig. 10 is a perspective view of an electrosurgical catheter system for removing body structures according to the present invention;

Fig. 11 illustrates the distal portion of an electrosurgical catheter for use with the system of Fig. 10;

Fig. 12A and 12B are cross-sectional and end views, respectively of a distal portion of a second electrosurgical catheter according to the present invention;

Figs. 13 and 14 illustrate electrosurgical instruments for removing cancerous or pre-cancerous tissue according to the present invention.

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## DESCRIPTION OF SPECIFIC EMBODIMENTS

The present invention provides systems and methods for selectively applying electrical energy to a target location within or on a patient's body. In particular, the present invention is useful for removing undesirable body structures while minimizing the spread of viable cells from the removed body structures. The methods and apparatus disclosed herein may be used in a wide variety of procedures, including open procedures, intravascular procedures, urology, laparascopy, arthroscopy, thoracoscopy, cardiac surgery or interventional cardiology procedures, dermatology, orthopedics, gynecology, otorhinolaryngology, spinal and neurologic procedures, oncology and the like. For convenience, the remaining disclosure will be directed specifically to the volumetric removal of cancerous or other infectious tissue, such as malignant tumors, congenital warts, surface lesions and the like.

In the present invention, high frequency (RF) electrical energy is applied to one or more electrode terminals in the presence of electrically conductive fluid to remove and/or modify the structure of tissue structures. Specifically, the tissue structures are volumetrically removed or ablated by converting the viable cells into non-viable atoms and molecules. In this procedure, a high frequency voltage difference is applied between one or more electrode terminal(s) and one or more return electrode(s) to develop high electric field intensities in the vicinity of the target tissue. The high electric field intensities adjacent the electrode terminal(s) lead to electric field induced molecular breakdown of target tissue through molecular dissociation (rather than thermal evaporation or carbonization). Applicant believes that the tissue structure is volumetrically removed through molecular disintegration of larger organic molecules into smaller molecules and/or atoms, such as hydrogen, oxygen, oxides of carbon, hydrocarbons and nitrogen compounds. This molecular disintegration completely removes the tissue structure, as opposed to dehydrating the tissue material by the removal of liquid within the cells of the tissue, as is typically the case with electrosurgical desiccation and vaporization.

The high electric field intensities may be generated by applying a high

frequency voltage that is sufficient to vaporize an electrically conducting fluid over at least a portion of the electrode terminal(s) in the region between the distal tip of the electrode terminal(s) and the target tissue. The electrically conductive fluid may be a liquid, such as isotonic saline or blood, delivered to the target site, or a viscous fluid, such as a gel, 5 applied to the target site. Since the vapor layer or vaporized region has a relatively high electrical impedance, it increases the voltage differential between the electrode terminal tip and the tissue and causes ionization within the vapor layer due to the presence of an ionizable species (e.g., sodium when isotonic saline is the electrically conducting fluid). This ionization, under optimal conditions, induces the discharge of energetic electrons and 10 photons from the vapor layer and to the surface of the target tissue. This energy may be in the form of energetic photons (e.g., ultraviolet radiation), energetic particles (e.g., electrons) or a combination thereof. A more detailed description of this phenomena, termed Coblation™ can be found in commonly assigned U.S. Patent No. 5,683,366 the complete disclosure of which is incorporated herein by reference.

15 The present invention applies high frequency (RF) electrical energy in an electrically conducting fluid environment to remove (i.e., resect, cut or ablate) a tissue structure, and to seal transected vessels within the region of the target tissue. The present invention is particularly useful for sealing larger arterial vessels, e.g., on the order of 1 mm or greater. In some embodiments, a high frequency power supply is provided having 20 an ablation mode, wherein a first voltage is applied to an electrode terminal sufficient to effect molecular dissociation or disintegration of the tissue, and a coagulation mode, wherein a second, lower voltage is applied to an electrode terminal (either the same or a different electrode) sufficient to achieve hemostasis of severed vessels within the tissue. In other embodiments, an electrosurgical instrument is provided having one or more 25 coagulation electrode(s) configured for sealing a severed vessel, such as an arterial vessel, and one or more electrode terminals configured for either contracting the collagen fibers within the tissue or removing (ablating) the tissue, e.g., by applying sufficient energy to the tissue to effect molecular dissociation. In the latter embodiments, the coagulation electrode(s) may be configured such that a single voltage can be applied to coagulate with the coagulation electrode(s), and to ablate with the electrode terminal(s). In other 30 embodiments, the power supply is combined with the coagulation instrument such that the coagulation electrode is used when the power supply is in the coagulation mode (low voltage), and the electrode terminal(s) are used when the power supply is in the ablation

mode (higher voltage).

In the method of the present invention, one or more electrode terminals are brought into close proximity to tissue at a target site, and the power supply is activated in the ablation mode such that sufficient voltage is applied between the electrode terminals and the return electrode to volumetrically remove the tissue through molecular dissociation, as described below. During this process, vessels within the tissue will be severed. Smaller vessels will be automatically sealed with the system and method of the present invention. Larger vessels, and those with a higher flow rate, such as arterial vessels, may not be automatically sealed in the ablation mode. In these cases, the severed vessels may be sealed by activating a control (e.g., a foot pedal) to reduce the voltage of the power supply into the coagulation mode. In this mode, the electrode terminals may be pressed against the severed vessel to provide sealing and/or coagulation of the vessel. Alternatively, a coagulation electrode located on the same or a different instrument may be pressed against the severed vessel. Once the vessel is adequately sealed, the surgeon activates a control (e.g., another foot pedal) to increase the voltage of the power supply back into the ablation mode.

The present invention is particularly useful for removing or ablating tissue around nerves, such as spinal or cranial nerves, e.g., the olfactory nerve on either side of the nasal cavity, the optic nerve within the optic and cranial canals, the palatine nerve within the nasal cavity, soft palate, uvula and tonsil the spinal cord and the surrounding dura mater, etc. One of the significant drawbacks with the prior art microdebriders and lasers is that these devices do not differentiate between the target tissue and the surrounding nerves or bone. Therefore, the surgeon must be extremely careful during these procedures to avoid damage to the bone or nerves within and around the nasal cavity. In the present invention, the Coblation™ process for removing tissue results in extremely small depths of collateral tissue damage as discussed above. This allows the surgeon to remove tissue close to a nerve without causing collateral damage to the nerve fibers.

In addition to the generally precise nature of the novel mechanisms of the present invention, applicant has discovered that the Coblation™ mechanism of the present invention can be manipulated to ablate or remove certain tissue structures, while having little effect on other tissue structures. As discussed above, the present invention uses a technique of vaporizing electrically conductive fluid to form a plasma layer or pocket around the electrode terminal(s), and then inducing the discharge of energy from this

plasma or vapor layer to break the molecular bonds of the tissue structure. Based on initial experiments, applicants believe that the free electrons within the ionized vapor layer are accelerated in the high electric fields near the electrode tip(s). When the density of the vapor layer (or within a bubble formed in the electrically conducting fluid) becomes 5 sufficiently low (i.e., less than approximately  $10^{20}$  atoms/cm<sup>3</sup> for aqueous solutions), the electron mean free path increases to enable subsequently injected electrons to cause impact ionization within these regions of low density (i.e., vapor layers or bubbles). Energy evolved by the energetic electrons (e.g., 4 to 5 eV) can subsequently bombard a molecule and break its bonds, dissociating a molecule into free radicals, which then combine into 10 final gaseous or liquid species.

The energy evolved by the energetic electrons may be varied by adjusting a variety of factors, such as: the number of electrode terminals; electrode size and spacing; electrode surface area; asperities and sharp edges on the electrode surfaces; electrode materials; applied voltage and power; current limiting means, such as inductors; electrical 15 conductivity of the fluid in contact with the electrodes; density of the fluid; and other factors. Accordingly, these factors can be manipulated to control the energy level of the excited electrons. Since different tissue structures have different molecular bonds, the present invention can be configured to break the molecular bonds of certain tissue, while having too low an energy to break the molecular bonds of other tissue. For example, 20 nerves usually comprise a connective tissue sheath, or epineurium, enclosing the bundles of nerve fibers to protect these nerve fibers. This protective tissue sheath comprises a fatty tissue (e.g., adipose tissue) having double bonds that require a substantially higher energy level than 4 to 5 eV to break. Accordingly, the present invention in its current configuration generally does not ablate or remove such fatty tissue. Of course, factors 25 may be changed such that these double bonds can also be broken in a similar fashion as the single bonds (e.g., increasing voltage or changing the electrode configuration to increase the current density at the electrode tips). A more complete description of this phenomena can be found in co-pending U.S. Patent Application 09/032,375, filed February 27, 1998 (Attorney Docket No. CB-3), the complete disclosure of which is incorporated herein by 30 reference.

The electrosurgical probe or catheter will comprise a shaft or a handpiece having a proximal end and a distal end which supports one or more electrode terminal(s). The shaft or handpiece may assume a wide variety of configurations, with the primary

purpose being to mechanically support the active electrode and permit the treating physician to manipulate the electrode from a proximal end of the shaft. The shaft may be rigid or flexible, with flexible shafts optionally being combined with a generally rigid external tube for mechanical support. Flexible shafts may be combined with pull wires, 5 shape memory actuators, and other known mechanisms for effecting selective deflection of the distal end of the shaft to facilitate positioning of the electrode array. The shaft will usually include a plurality of wires or other conductive elements running axially therethrough to permit connection of the electrode array to a connector at the proximal end of the shaft. Specific shaft designs will be described in detail in connection with the 10 figures hereinafter.

The current flow path between the electrode terminal(s) and the return electrode(s) may be generated by submerging the tissue site in an electrical conducting fluid (e.g., within a viscous fluid, such as an electrically conductive gel) or by directing an electrically conducting fluid along a fluid path to the target site (i.e., a liquid, such as 15 isotonic saline, or a gas, such as argon). This latter method is particularly effective in a dry environment (i.e., the tissue is not submerged in fluid) because the electrically conducting fluid provides a suitable current flow path from the electrode terminal to the return electrode.

In some procedures, it may also be necessary to retrieve or aspirate the 20 electrically conductive fluid after it has been directed to the target site. In addition, it may be desirable to aspirate small pieces of tissue that are not completely disintegrated by the high frequency energy, or other fluids at the target site, such as blood, mucus, the gaseous products of ablation, etc. Accordingly, the system of the present invention will usually include a suction lumen in the probe, or on another instrument, for aspirating fluids from 25 the target site. In addition, the invention may include one or more aspiration electrode(s) coupled to the distal end of the suction lumen for ablating, or at least reducing the volume of, non-ablated tissue fragments that are aspirated into the lumen. The aspiration electrode(s) function mainly to inhibit clogging of the lumen that may otherwise occur as larger tissue fragments are drawn therein. The aspiration electrode(s) may be different 30 from the ablation electrode terminal(s), or the same electrode(s) may serve both functions. A more complete description of instruments incorporating aspiration electrode(s) can be found in commonly assigned, co-pending provisional patent application No. 60/010,382,

filed January 21, 1998, the complete disclosure of which is incorporated herein by reference.

The present invention may use a single active electrode terminal or an electrode array distributed over a contact surface of a probe. In the latter embodiment, the 5 electrode array usually includes a plurality of independently current-limited and/or power-controlled electrode terminals to apply electrical energy selectively to the target tissue while limiting the unwanted application of electrical energy to the surrounding tissue and environment resulting from power dissipation into surrounding electrically conductive fluids, such as blood, normal saline, electrically conductive gel and the like. The electrode 10 terminals may be independently current-limited by isolating the terminals from each other and connecting each terminal to a separate power source that is isolated from the other electrode terminals. Alternatively, the electrode terminals may be connected to each other at either the proximal or distal ends of the probe to form a single wire that couples to a power source.

15 The active electrode(s) are typically mounted in an electrically insulating electrode support that extends from the electrosurgical probe. In some embodiments, the electrode support comprises a plurality of wafer layers bonded together, e.g., by a glass adhesive or the like, or a single wafer. The wafer layer(s) have conductive strips printed thereon to form the electrode terminal(s) and the return electrode(s). In one embodiment, 20 the proximal end of the wafer layer(s) will have a number of holes extending from the conductor strips to an exposed surface of the wafer layers for connection to electrical conductor lead traces in the electrosurgical probe or handpiece. The wafer layers preferably comprise a ceramic material, such as alumina, and the electrode will preferably comprise a metallic material, such as gold, copper, platinum, palladium, tungsten, silver 25 or the like. Suitable multilayer ceramic electrodes are commercially available from e.g., VisPro Corporation of Beaverton, Oregon. A more complete description of such electrode supports can be found in co-pending, commonly assigned U.S. Patent Application No. 08/977,845.

30 In one configuration, each individual electrode terminal in the electrode array is electrically insulated from all other electrode terminals in the array within said probe and is connected to a power source which is isolated from each of the other electrode terminals in the array or to circuitry which limits or interrupts current flow to the electrode terminal when low resistivity material (e.g., blood, electrically conductive saline

irrigant or electrically conductive gel) causes a lower impedance path between the return electrode and the individual electrode terminal. The isolated power sources for each individual electrode terminal may be separate power supply circuits having internal impedance characteristics which limit power to the associated electrode terminal when a 5 low impedance return path is encountered. By way of example, the isolated power source may be a user selectable constant current source. In this embodiment, lower impedance paths will automatically result in lower resistive heating levels since the heating is proportional to the square of the operating current times the impedance. Alternatively, a single power source may be connected to each of the electrode terminals through 10 independently actuatable switches, or by independent current limiting elements, such as inductors, capacitors, resistors and/or combinations thereof. The current limiting elements may be provided in the probe, connectors, cable, controller or along the conductive path from the controller to the distal tip of the probe. Alternatively, the resistance and/or capacitance may occur on the surface of the active electrode terminal(s) due to oxide layers 15 which form selected electrode terminals (e.g., titanium or a resistive coating on the surface of metal, such as platinum).

The tip region of the probe may comprise many independent electrode terminals designed to deliver electrical energy in the vicinity of the tip. The selective application of electrical energy to the conductive fluid is achieved by connecting each 20 individual electrode terminal and the return electrode to a power source having independently controlled or current limited channels. The return electrode(s) may comprise a single tubular member of conductive material proximal to the electrode array at the tip which also serves as a conduit for the supply of the electrically conducting fluid between the active and return electrodes. Alternatively, the probe may comprise an array 25 of return electrodes at the distal tip of the probe (together with the active electrodes) to maintain the electric current at the tip. The application of high frequency voltage between the return electrode(s) and the electrode array results in the generation of high electric field intensities at the distal tips of the electrode terminals with conduction of high frequency current from each individual electrode terminal to the return electrode. The current flow 30 from each individual electrode terminal to the return electrode(s) is controlled by either active or passive means, or a combination thereof, to deliver electrical energy to the surrounding conductive fluid while minimizing energy delivery to surrounding (non-target) tissue.

The application of a high frequency voltage between the return electrode(s) and the electrode terminal(s) for appropriate time intervals effects cutting, removing, ablating, shaping, contracting or otherwise modifying the target tissue. The tissue volume over which energy is dissipated (*i.e.*, a high current density exists) may be precisely controlled, for example, by the use of a multiplicity of small electrode terminals whose effective diameters or principal dimensions range from about 5 mm to 0.01 mm, preferably from about 2 mm to 0.05 mm, and more preferably from about 1 mm to 0.1 mm. 5 Electrode areas for both circular and non-circular terminals will have a contact area (per electrode terminal) below 25 mm<sup>2</sup>, preferably being in the range from 0.0001 mm<sup>2</sup> to 1 mm<sup>2</sup>, and more preferably from 0.005 mm<sup>2</sup> to .5 mm<sup>2</sup>. The circumscribed area of the 10 electrode array is in the range from 0.25 mm<sup>2</sup> to 75 mm<sup>2</sup>, preferably from 0.5 mm<sup>2</sup> to 40 mm<sup>2</sup>, and will usually include at least two isolated electrode terminals, preferably at least 15 five electrode terminals, often greater than 10 electrode terminals and even 50 or more electrode terminals, disposed over the distal contact surfaces on the shaft. The use of small diameter electrode terminals increases the electric field intensity and reduces the extent or depth of tissue heating as a consequence of the divergence of current flux lines which emanate from the exposed surface of each electrode terminal.

The area of the tissue treatment surface can vary widely, and the tissue treatment surface can assume a variety of geometries, with particular areas and geometries 20 being selected for specific applications. Active electrode surfaces can have areas in the range from 0.25 mm<sup>2</sup> to 75 mm<sup>2</sup>, usually being from about 0.5 mm<sup>2</sup> to 40 mm<sup>2</sup>. The geometries can be planar, concave, convex, hemispherical, conical, linear "in-line" array or virtually any other regular or irregular shape. Most commonly, the active electrode(s) or electrode terminal(s) will be formed at the distal tip of the electrosurgical probe shaft, 25 frequently being planar, disk-shaped, or hemispherical surfaces for use in reshaping procedures or being linear arrays for use in cutting. Alternatively or additionally, the active electrode(s) may be formed on lateral surfaces of the electrosurgical probe shaft (*e.g.*, in the manner of a spatula), facilitating access to certain body structures in endoscopic procedures.

30 In the representative embodiments, the electrode terminals comprise substantially rigid wires protruding outward from the tissue treatment surface of the electrode support member. Usually, the wires will extend about 0.1 to 4.0 mm, preferably about 0.2 to 1 mm, from the distal surface of the support member. In the exemplary

embodiments, the electrosurgical probe includes between about two to fifty electrically isolated electrode terminals, and preferably between about three to twenty electrode terminals.

The electrically conducting fluid should have a threshold conductivity to provide a suitable conductive path between the return electrode(s) and the electrode terminal(s). The electrical conductivity of the fluid (in units of millSiemens per centimeter or mS/cm) will usually be greater than 0.2 mS/cm, preferably will be greater than 2 mS/cm and more preferably greater than 10 mS/cm. In an exemplary embodiment, the electrically conductive fluid is isotonic saline, which has a conductivity of about 17 mS/cm.

In some embodiments, the electrode support and the fluid outlet may be recessed from an outer surface of the probe or handpiece to confine the electrically conductive fluid to the region immediately surrounding the electrode support. In addition, the shaft may be shaped so as to form a cavity around the electrode support and the fluid outlet. This helps to assure that the electrically conductive fluid will remain in contact with the electrode terminal(s) and the return electrode(s) to maintain the conductive path therebetween. In addition, this will help to maintain a vapor or plasma layer between the electrode terminal(s) and the tissue at the treatment site throughout the procedure, which reduces the thermal damage that might otherwise occur if the vapor layer were extinguished due to a lack of conductive fluid. Provision of the electrically conductive fluid around the target site also helps to maintain the tissue temperature at desired levels.

The voltage applied between the return electrode(s) and the electrode array will be at high or radio frequency, typically between about 5 kHz and 20 MHz, usually being between about 30 kHz and 2.5 MHz, preferably being between about 50 kHz and 500 kHz, more preferably less than 350 kHz, and most preferably between about 100 kHz and 200 kHz. The RMS (root mean square) voltage applied will usually be in the range from about 5 volts to 1000 volts, preferably being in the range from about 10 volts to 500 volts depending on the electrode terminal size, the operating frequency and the operation mode of the particular procedure or desired effect on the tissue (i.e., contraction, coagulation or ablation). Typically, the peak-to-peak voltage will be in the range of 10 to 2000 volts, preferably in the range of 20 to 1200 volts and more preferably in the range of about 40 to 800 volts (again, depending on the electrode size, the operating frequency and the operation mode).

As discussed above, the voltage is usually delivered in a series of voltage pulses or alternating current of time varying voltage amplitude with a sufficiently high frequency (e.g., on the order of 5 kHz to 20 MHz) such that the voltage is effectively applied continuously (as compared with e.g., lasers claiming small depths of necrosis, 5 which are generally pulsed about 10 to 20 Hz). In addition, the duty cycle (i.e., cumulative time in any one-second interval that energy is applied) is on the order of about 50% for the present invention, as compared with pulsed lasers which typically have a duty cycle of about 0.0001%.

The preferred power source of the present invention delivers a high 10 frequency current selectable to generate average power levels ranging from several milliwatts to tens of watts per electrode, depending on the volume of target tissue being heated, and/or the maximum allowed temperature selected for the probe tip. The power source allows the user to select the voltage level according to the specific requirements of a particular FESS procedure, arthroscopic surgery, dermatological procedure, ophthalmic 15 procedures, open surgery or other endoscopic surgery procedure. A description of a suitable power source can be found in U.S. Patent Application No. 09/058,571 (Attorney Docket CB-2), the complete disclosure of which has been incorporated herein by reference.

The power source may be current limited or otherwise controlled so that 20 undesired heating of the target tissue or surrounding (non-target) tissue does not occur. In a presently preferred embodiment of the present invention, current limiting inductors are placed in series with each independent electrode terminal, where the inductance of the inductor is in the range of 10uH to 50,000uH, depending on the electrical properties of the target tissue, the desired tissue heating rate and the operating frequency. Alternatively, 25 capacitor-inductor (LC) circuit structures may be employed, as described previously in co-pending PCT application No. PCT/US94/05168, the complete disclosure of which is incorporated herein by reference. Additionally, current limiting resistors may be selected. Preferably, these resistors will have a large positive temperature coefficient of resistance so that, as the current level begins to rise for any individual electrode terminal in contact 30 with a low resistance medium (e.g., saline irrigant or conductive gel), the resistance of the current limiting resistor increases significantly, thereby minimizing the power delivery from said electrode terminal into the low resistance medium (e.g., saline irrigant or conductive gel).

It should be clearly understood that the invention is not limited to electrically isolated electrode terminals, or even to a plurality of electrode terminals. For example, the array of active electrode terminals may be connected to a single lead that extends through the probe shaft to a power source of high frequency current.

5 Alternatively, the probe may incorporate a single electrode that extends directly through the probe shaft or is connected to a single lead that extends to the power source. The active electrode may have a ball shape (e.g., for tissue vaporization and desiccation), a twizzle shape (for vaporization and needle-like cutting), a spring shape (for rapid tissue debulking and desiccation), a twisted metal shape, an annular or solid tube shape or the like. Alternatively, the electrode may comprise a plurality of filaments, a rigid or flexible brush electrode (for debulking a tumor, such as a fibroid, bladder tumor or a prostate adenoma), a side-effect brush electrode on a lateral surface of the shaft, a coiled electrode or the like. In one embodiment, the probe comprises a single active electrode terminal that extends from an insulating member, e.g., ceramic, at the distal end of the probe. The 10 insulating member is preferably a tubular structure that separates the active electrode terminal from a tubular or annular return electrode positioned proximal to the insulating member and the active electrode.

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Referring to Fig. 1, an exemplary electrosurgical system 11 for removing viable tissue will now be described in detail. Electrosurgical system 11 generally comprises an electrosurgical handpiece or probe 10 connected to a power supply 28 for providing high frequency voltage to a target site and a fluid source 21 for supplying electrically conducting fluid 50 to probe 10. In addition, electrosurgical system 11 may include an endoscope (not shown) with a fiber optic head light for viewing the surgical site, if desired. The endoscope may be integral with probe 10, or it may be part of a 20 separate instrument. The system 11 may also include a vacuum source (not shown) for coupling to a suction lumen or tube 220 (see Fig. 2) in the probe 10 for aspirating the target site.

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As shown, probe 10 generally includes a proximal handle 19 and an elongate shaft 18 having an array 12 of electrode terminals 58 at its distal end. A 30 connecting cable 34 has a connector 26 for electrically coupling the electrode terminals 58 to power supply 28. The electrode terminals 58 are electrically isolated from each other and each of the terminals 58 is connected to an active or passive control network within power supply 28 by means of a plurality of individually insulated conductors (not shown).

A fluid supply tube 15 is connected to a fluid tube 14 of probe 10 for supplying electrically conductive fluid 50 to the target site. Conductive fluid 50 may be driven by gravity or with a suitable pump.

Power supply 28 has an operator controllable voltage level adjustment 30 to change the applied voltage level, which is observable at a voltage level display 32. Power supply 28 also includes first, second and third foot pedals 37, 38, 39 and a cable 36 which is removably coupled to power supply 28. The foot pedals 37, 38, 39 allow the surgeon to remotely adjust the energy level applied to electrode terminals 58. In an exemplary embodiment, first foot pedal 37 is used to place the power supply into the "ablation" mode and second foot pedal 38 places power supply 28 into the "subablation" mode (e.g., coagulation, tissue contraction or the like). The third foot pedal 39 allows the user to adjust the voltage level within the "ablation" mode. In the ablation mode, a sufficient voltage is applied to the electrode terminals to establish the requisite conditions for molecular dissociation of the tissue (i.e., vaporizing a portion of the electrically conductive fluid, ionizing charged particles within the vapor layer and accelerating these charged particles against the tissue). As discussed above, the requisite voltage level for ablation will vary depending on the number, size, shape and spacing of the electrodes, the distance in which the electrodes extend from the support member, etc. Once the surgeon places the power supply in the "ablation" mode, voltage level adjustment 30 or third foot pedal 39 may be used to adjust the voltage level to adjust the degree or aggressiveness of the ablation.

Of course, it will be recognized that the voltage and modality of the power supply may be controlled by other input devices. However, applicant has found that foot pedals are convenient methods of controlling the power supply while manipulating the probe during a surgical procedure.

In the subablation mode, the power supply 28 applies a low enough voltage to the electrode terminals to avoid vaporization of the electrically conductive fluid and subsequent molecular dissociation of the tissue. The surgeon may automatically toggle the power supply between the ablation and subablation modes by alternatively stepping on foot pedals 37, 38, respectively. This allows, for example, the surgeon to quickly move between coagulation and ablation in situ, without having to remove his/her concentration from the surgical field or without having to request an assistant to switch the power supply. By way of example, as the surgeon is sculpting soft tissue in the ablation mode,

the probe typically will simultaneously seal and/or coagulation small severed vessels within the tissue. However, larger vessels, or vessels with high fluid pressures (e.g., arterial vessels) may not be sealed in the ablation mode. Accordingly, the surgeon can simply step on foot pedal 38, automatically lowering the voltage level below the threshold level for 5 ablation, and apply sufficient pressure onto the severed vessel for a sufficient period of time to seal and/or coagulate the vessel. After this is completed, the surgeon may quickly move back into the ablation mode by stepping on foot pedal 37. A specific design of a suitable power supply for use with the present invention can be found in co-pending Patent Applications 09/058,571 and 09/058,336, filed April 10, 1998 (Attorney Docket Nos. CB-10 2 and CB-4), previously incorporated herein by reference.

Figs. 2-5 illustrate an exemplary electrosurgical probe 90 constructed according to the principles of the present invention. As shown in Fig. 2, probe 90 generally includes an elongated shaft 100 which may be flexible or rigid, a handle 204 coupled to the proximal end of shaft 100 and an electrode support member 102 coupled to 15 the distal end of shaft 100. Shaft 100 preferably comprises a plastic material that is easily molded into the shape shown in Fig. 1. Alternatively, shaft 100 may comprise an electrically conducting material, usually metal, which is selected from the group comprising tungsten, stainless steel alloys, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys. In this embodiment, shaft 100 includes 20 an electrically insulating jacket, which is typically formed as one or more electrically insulating sheaths or coatings, such as polytetrafluoroethylene, polyimide, and the like. The provision of the electrically insulating jacket over the shaft prevents direct electrical contact between these metal elements and any adjacent body structure or the surgeon. Such direct electrical contact between a body structure (e.g., tendon) and an exposed 25 electrode could result in unwanted heating and necrosis of the structure at the point of contact causing necrosis.

Handle 204 typically comprises a plastic material that is easily molded into a suitable shape for handling by the surgeon. Handle 204 defines an inner cavity (not shown) that houses the electrical connections 250 (Fig. 5), and provides a suitable interface 30 for connection to an electrical connecting cable 22 (see Fig. 1). Electrode support member 102 extends from the distal end of shaft 100 (usually about 1 to 20 mm), and provides support for a plurality of electrically isolated electrode terminals 104 (see Figs. 3 and 4). As shown in Fig. 2, a fluid tube 233 extends through an opening in handle 204, and

includes a connector 235 for connection to a fluid supply source, for supplying electrically conductive fluid to the target site. Depending on the configuration of the distal surface of shaft 100, fluid tube 233 may extend through a single lumen (not shown) in shaft 100, or it may be coupled to a plurality of lumens (also not shown) that extend through shaft 100 to a plurality of openings at its distal end. In the representative embodiment, fluid tube 233 extends along the exterior of shaft 100 to a point just proximal of return electrode 112 (see Fig. 4). In this embodiment, the fluid is directed through an opening 237 past return electrode 112 to the electrode terminals 104. Probe 90 may also include a valve 17 (Fig. 1) or equivalent structure for controlling the flow rate of the electrically conducting fluid to the target site.

As shown in Fig. 2, the distal portion of shaft 100 is preferably bent to improve access to the operative site of the tissue being treated. Electrode support member 102 has a substantially planar tissue treatment surface 212 (Fig. 3) that is usually at an angle of about 10 to 90 degrees relative to the longitudinal axis of shaft 100, although the shaft may have no angle at all. In alternative embodiments, the distal portion of shaft 100 comprises a flexible material which can be deflected relative to the longitudinal axis of the shaft. Such deflection may be selectively induced by mechanical tension of a pull wire, for example, or by a shape memory wire that expands or contracts by externally applied temperature changes.

In the embodiment shown in Figs. 2-5, probe 90 includes a return electrode 112 for completing the current path between electrode terminals 104 and a high frequency power supply 28 (see Fig. 1). As shown, return electrode 112 preferably comprises an annular conductive band coupled to the distal end of shaft 100 slightly proximal to tissue treatment surface 212 of electrode support member 102, typically about 0.5 to 10 mm and more preferably about 1 to 10 mm. In embodiments where the shaft comprises a conductive material, the shaft will have an exposed portion that functions as the return electrode. Return electrode 112 is coupled to a connector (not shown) that extends to the proximal end of probe 10, where it is suitably connected to power supply 10 (Fig. 1).

As shown in Fig. 2, return electrode 112 is not directly connected to electrode terminals 104. To complete this current path so that electrode terminals 104 are electrically connected to return electrode 112, electrically conducting fluid (e.g., isotonic saline) is caused to flow therebetween. In the representative embodiment, the electrically conducting fluid is delivered through fluid tube 233 to opening 237, as described above.

Alternatively, the fluid may be delivered by a fluid delivery element (not shown) that is separate from probe 90. In arthroscopic surgery, for example, the body cavity will be flooded with isotonic saline and the probe 90 will be introduced into this flooded cavity. Electrically conducting fluid will be continually resupplied to maintain the conduction path 5 between return electrode 112 and electrode terminals 104.

In alternative embodiments, the fluid path may be formed in probe 90 by, for example, an inner lumen or an annular gap between the return electrode and a tubular support member within shaft 100 (see Fig. 6). This annular gap may be formed near the perimeter of the shaft 100 such that the electrically conducting fluid tends to flow radially inward towards the target site, or it may be formed towards the center of shaft 100 so that the fluid flows radially outward. In both of these embodiments, a fluid source (e.g., a bag 10 of fluid elevated above the surgical site or suitable pumping device), is coupled to probe 90 via a fluid supply tube (not shown) that may or may not have a controllable valve.

Referring to Fig. 3, the electrically isolated electrode terminals 104 are 15 spaced apart over tissue treatment surface 212 of electrode support member 102. The tissue treatment surface and individual electrode terminals 104 will usually have dimensions within the ranges set forth above. In the representative embodiment, the tissue treatment surface 212 has a circular cross-sectional shape with a diameter in the range of about 1 to 20 mm. The individual electrode terminals 104 preferably extend outward from 20 tissue treatment surface 212 by a distance of about 0.0 to 4 mm, usually about 0.2 to 2 mm. Applicant has found that this configuration increases the high electric field intensities and associated current densities around electrode terminals 104 to facilitate the ablation of tissue as described in detail above.

In the embodiment of Figs. 2-5, the probe includes a single, larger opening 25 209 in the center of tissue treatment surface 212, and a plurality of electrode terminals (e.g., about 3 to 15 electrode terminals) around the perimeter of surface 212 (see Fig. 3). Alternatively, the probe may include a single, annular, or partially annular, electrode terminal at the perimeter of the tissue treatment surface. The central opening 209 is 30 coupled to a suction lumen 215 within shaft 100 and a suction tube 211 (Fig. 2) for aspirating tissue, fluids, calcified fragments and/or gases from the target site. In this embodiment, the electrically conductive fluid generally flows radially inward past electrode terminals 104 and then back through the opening 209. Aspirating the electrically conductive fluid during surgery allows the surgeon to see the target site, and it prevents the

dispersal of gases, tissue fragments and/or calcified deposits into the patient's body.

In some embodiments, the probe 90 will also include one or more aspiration electrode(s) (not shown) coupled to the aspiration lumen 215 for inhibiting clogging during aspiration of tissue fragments from the surgical site. A more complete description of these 5 embodiments can be found in commonly assigned co-pending Application No. 09/010,382, filed January 21, 1998 (Attorney Docket No. A-6), the complete disclosure of which is incorporated herein by reference for all purposes.

Fig. 5 illustrates the electrical connections 250 within handle 204 for coupling electrode terminals 104 and return electrode 112 to the power supply 28. As 10 shown, a plurality of wires 252 extend through shaft 100 to couple terminals 104 to a plurality of pins 254, which are plugged into a connector block 256 for coupling to a connecting cable 22 (Fig. 1). Similarly, return electrode 112 is coupled to connector block 256 via a wire 258 and a pin 260.

According to the present invention, the probe 90 further includes an 15 identification element that is characteristic of the particular electrode assembly so that the same power supply 28 can be used for different electrosurgical operations. In one embodiment, for example, the probe 90 includes a voltage reduction element or a voltage reduction circuit for reducing the voltage applied between the electrode terminals 104 and the return electrode 112. The voltage reduction element serves to reduce the voltage 20 applied by the power supply so that the voltage between the electrode terminals and the return electrode is low enough to avoid excessive power dissipation into the electrically conducting medium and/or ablation of the soft tissue at the target site. The voltage reduction element primarily allows the electrosurgical probe 90 to be compatible with other ArthroCare generators that are adapted to apply higher voltages for ablation or 25 vaporization of tissue. For contraction of tissue, for example, the voltage reduction element will serve to reduce a voltage of about 100 to 135 volts rms (which is a setting of 1 on the ArthroCare Models 970, 980 and 2000 Generators) to about 45 to 60 volts rms, which is a suitable voltage for contraction of tissue without ablation (e.g., molecular dissociation) of the tissue.

30 Of course, for some procedures, the probe will typically not require a voltage reduction element. Alternatively, the probe may include a voltage increasing element or circuit, if desired.

In the representative embodiment, the voltage reduction element is a

dropping capacitor 262 which has first leg 264 coupled to the return electrode wire 258 and a second leg 266 coupled to connector block 256. Of course, the capacitor may be located in other places within the system, such as is in, or distributed along the length of: (1) the cable; (2) in the generator; (3) in the connector, etc. In addition, it will be 5 recognized that other voltage reduction elements, such as diodes, transistors, inductors, resistors, capacitors or combinations thereof, may be used in conjunction with the present invention. For example, the probe 90 may include a coded resistor (not shown) that is constructed to lower the voltage applied between return electrode 112 and electrode terminals 104 to a suitable level for contraction of tissue. In addition, electrical circuits 10 may be employed for this purpose.

Alternatively or additionally, the cable 22 that couples the power supply 10 to the probe 90 may be used as a voltage reduction element. The cable has an inherent capacitance that can be used to reduce the power supply voltage if the cable is placed into the electrical circuit between the power supply, the electrode terminals and the return 15 electrode. In this embodiment, the cable 22 may be used alone, or in combination with one of the voltage reduction elements discussed above, e.g., a capacitor.

Further, it should be noted that the present invention can be used with a power supply that is adapted to apply a voltage within the selected range for treatment of tissue. In this embodiment, a voltage reduction element or circuitry may not be desired. 20

Figs. 7A-7C schematically illustrate the distal portion of three different embodiments of probe 90 according to the present invention. As shown in 7A, electrode terminals 104 are anchored in a support matrix 102 of suitable insulating material (e.g., ceramic or glass material, such as alumina, silicon nitride zirconia and the like) which could be formed at the time of manufacture in a flat, hemispherical or other shape 25 according to the requirements of a particular procedure. The preferred support matrix material is alumina, available from Kyocera Industrial Ceramics Corporation, Elk Grove, Illinois, because of its high thermal conductivity, good thermal shock resistance, good electrically insulative properties, high flexural modulus, resistance to carbon tracking, biocompatibility, and high melting point. The support matrix 102 is adhesively joined to a 30 tubular support member 78 that extends most or all of the distance between matrix 102 and the proximal end of probe 90. Tubular member 78 preferably comprises an electrically insulating material, such as an epoxy or silicone-based material.

In a preferred construction technique, electrode terminals 104 extend

through pre-formed openings in the support matrix 102 so that they protrude above tissue treatment surface 212 by the desired distance. The electrodes are then bonded to the tissue treatment surface 212 of support matrix 102, typically by an inorganic sealing material 80.

Sealing material 80 is selected to provide effective electrical insulation, and good adhesion to both the alumina matrix 102 and the electrode terminals (e.g., titanium, tungsten, molybdenum, platinum, etc.). Sealing material 80 additionally should have a compatible thermal expansion coefficient and a melting point well below that of the metal electrode terminals and the ceramic support matrix, typically being a glass or glass ceramic.

In the embodiment shown in Fig. 7A, return electrode 112 comprises an annular member positioned around the exterior of shaft 100 of probe 90. Return electrode 90 may fully or partially circumscribe tubular support member 78 to form an annular gap 54 therebetween for flow of electrically conducting fluid 50 therethrough, as discussed below. Gap 54 preferably has a width in the range of 0.1 mm to 4 mm. Alternatively, probe may include a plurality of longitudinal ribs between support member 78 and return electrode 112 to form a plurality of fluid lumens extending along the perimeter of shaft 100. In this embodiment, the plurality of lumens will extend to a plurality of openings.

Return electrode 112 is disposed within an electrically insulative jacket 18, which is typically formed as one or more electrically insulative sheaths or coatings, such as polytetrafluoroethylene, polyamide, and the like. The provision of the electrically insulative jacket 18 over return electrode 112 prevents direct electrical contact between return electrode 112 and any adjacent body structure. Such direct electrical contact between a body structure (e.g., tendon) and an exposed electrode member 112 could result in unwanted heating and necrosis of the structure at the point of contact causing necrosis.

As shown in Fig. 7A, return electrode 112 is not directly connected to electrode terminals 104. To complete this current path so that terminals 104 are electrically connected to return electrode 112, electrically conducting fluid 50 (e.g., isotonic saline) is caused to flow along fluid path(s) 83. Fluid path 83 is formed by annular gap 54 between outer return electrode 112 and tubular support member 78. The electrically conducting fluid 50 flowing through fluid path 83 provides a pathway for electrical current flow between electrode terminals 104 and return electrode 112, as illustrated by the current flux lines 60 in Fig. 6A. When a voltage difference is applied between electrode terminals 104 and return electrode 112, high electric field intensities will be generated at the distal tips of terminals 104 with current flow from terminals 104

through the target tissue to the return electrode, the high electric field intensities causing ablation of tissue 52 in zone 88.

Fig. 7B illustrates another alternative embodiment of electrosurgical probe 90 which has a return electrode 112 positioned within tubular member 78. Return electrode 112 is preferably a tubular member defining an inner lumen 57 for allowing electrically conducting fluid 50 (e.g., isotonic saline) to flow therethrough in electrical contact with return electrode 112. In this embodiment, a voltage difference is applied between electrode terminals 104 and return electrode 112 resulting in electrical current flow through the electrically conducting fluid 50 as shown by current flux lines 60 (Fig. 3). As a result of the applied voltage difference and concomitant high electric field intensities at the tips of electrode terminals 104, tissue 52 becomes ablated or transected in zone 88.

Fig. 7C illustrates another embodiment of probe 90 that is a combination of the embodiments in Figs. 7A and 7B. As shown, this probe includes both an inner lumen 15 57 and an outer gap or plurality of outer lumens 54 for flow of electrically conductive fluid. In this embodiment, the return electrode 112 may be positioned within tubular member 78 as in Fig. 7B, outside of tubular member 78 as in Fig. 7A, or in both locations.

Fig. 8 illustrates the current flux lines associated with an electric field 120 applied between the active and return electrodes 104, 112 when a voltage is applied therebetween. As shown, the electric field intensity is substantially higher in the region 88 at the tip of the electrode 58 because the current flux lines are concentrated in these regions. This high electric field intensity leads to induced molecular breakdown of the target tissue through molecular dissociation. As a result of the applied voltage difference 25 between electrode terminal(s) 104 and the target tissue 52 (i.e., the voltage gradient across the plasma layer 124), charged particles (not shown) in the plasma (viz., electrons) are accelerated towards the tissue. At sufficiently high voltage differences, these charged particles gain sufficient energy to cause dissociation of the molecular bonds within tissue structures. This molecular dissociation is accompanied by the volumetric removal (i.e., 30 ablative sublimation) of tissue and the production of low molecular weight gases 126 (see Fig. 9), such as oxygen, nitrogen, carbon dioxide, hydrogen and methane. The short range of the accelerated charged particles within the tissue confines the molecular

dissociation process to the surface layer to minimize damage and necrosis to the underlying tissue.

Referring to Figs. 10-12, the electrosurgical device according to the present invention may also be configured as an elongate catheter system 400 including portions 5 with sufficient flexibility to permit introduction into the body and to the target site through one or more vascular lumen(s). As shown in Fig. 10, a catheter system 400 generally comprises an electrosurgical catheter 460 connected to a power supply 28 by an interconnecting cable 486 for providing high frequency voltage to a target tissue site and an irrigant reservoir or source 600 for providing electrically conducting fluid to the target 10 site. Catheter 460 generally comprises an elongate, flexible shaft body 462 including a tissue removing or ablating region 464 at the distal end of body 462. The proximal portion of catheter 460 includes a multi-lumen fitment 614 which provides for interconnections between lumens and electrical leads within catheter 460 and conduits and cables proximal to fitment 614. By way of example, a catheter electrical connector 496 is removably 15 connected to a distal cable connector 494 which, in turn, is removably connectable to generator 28 through connector 492. One or more electrically conducting lead wires (not shown) within catheter 460 extend between one or more active electrodes 463 at tissue ablating region 464 and one or more corresponding electrical terminals (also not shown) in catheter connector 496 via active electrode cable branch 487. Similarly, one or more 20 return electrodes 466 at tissue ablating region 464 are coupled to a return electrode cable branch 489 of catheter connector 496 by lead wires (not shown). Of course, a single cable branch (not shown) may be used for both active and return electrodes.

Catheter body 462 may include reinforcing fibers or braids (not shown) in the walls of at least the distal ablation region 464 of body 462 to provide responsive torque 25 control for rotation of electrode terminals during tissue engagement. This rigid portion of the catheter body 462 preferably extends only about 7 to 10 mm while the remainder of the catheter body 462 is flexible to provide good trackability during advancement and positioning of the electrodes adjacent target tissue.

Conductive fluid 30 is provided to tissue ablation region 464 of catheter 460 30 via a lumen (not shown in Fig. 10) within catheter 460. Fluid is supplied to lumen from the source along a conductive fluid supply line 602 and a conduit 603, which is coupled to the inner catheter lumen at multi-lumen fitment 614. The source of conductive fluid (e.g., isotonic saline) may be an irrigant pump system (not shown) or a gravity-driven supply,

such as an irrigant reservoir 600 positioned several feet above the level of the patient and tissue ablating region 8. A control valve 604 may be positioned at the interface of fluid supply line 602 and conduit 603 to allow manual control of the flow rate of electrically conductive fluid 30. Alternatively, a metering pump or flow regulator may be used to precisely control the flow rate of the conductive fluid.

System 400 further includes an aspiration or vacuum system (not shown) to aspirate liquids and gases from the target site. The aspiration system will usually comprise a source of vacuum coupled to fitment 614 by a aspiration connector 605.

Figs. 11 and 12 illustrate the working end 464 of an electrosurgical catheter 460 constructed according to the principles of the present invention. As shown in Fig. 11, catheter 460 generally includes an elongated shaft 462 which may be flexible or rigid, and an electrode support member 620 coupled to the distal end of shaft 462. Electrode support member 620 extends from the distal end of shaft 462 (usually about 1 to 20 mm), and provides support for a plurality of electrically isolated electrode terminals 463. Electrode support member 620 and electrode terminals 463 are preferably secured to a tubular support member 626 within shaft 460 by adhesive 630.

The electrode terminals 463 may be constructed using round, square, rectangular or other shaped conductive metals. By way of example, the electrode terminal materials may be selected from the group including stainless steel, tungsten and its alloys, molybdenum and its alloys, titanium and its alloys, nickel-based alloys, as well as platinum and its alloys. Electrode support member 620 is preferably a ceramic, glass or glass/ceramic composition (e.g., aluminum oxide, titanium nitride). Alternatively, electrode support member 620 may include the use of high-temperature biocompatible plastics such as polyether-ether-keytone (PEEK) manufactured by Vitrex International Products, Inc. or polysulfone manufactured by GE Plastics. The adhesive 630 may, by way of example, be an epoxy (e.g., Master Bond EP42HT manufactured by Master Bond) or a silicone-based adhesive.

As shown in Fig. 12B, a total of 7 circular active electrodes or electrode terminals 463 are shown in a symmetrical pattern having an active electrode diameter,  $D_1$  in the range from 0.05 mm to 1.5 mm, more preferably in the range from 0.1 mm to 0.75 mm. The interelectrode spacings,  $W_1$  and  $W_2$  are preferably in the range from 0.1 mm to 1.5 mm and more preferably in the range from 0.2 mm to 0.75 mm. The distance between the outer perimeter of the electrode terminal 463 and the perimeter of the electrode support

member,  $W_3$  is preferably in the range from 0.1 mm to 1.5 mm and more preferably in the range from 0.2 mm to 0.75 mm. The overall diameter,  $D_2$  of the working end 464 of catheter body 462 is preferably in the range from 0.5 mm to 10 mm and more preferably in the range from 0.5 mm to 5 mm. As discussed above, the shape of the active electrodes 5 may be round, square, triangular, hexagonal, rectangular, tubular, flat strip and the like and may be arranged in a circularly symmetric pattern as shown in Fig. 12B or may, by way of example, be arranged in a rectangular pattern, square pattern, or strip.

Catheter body 462 includes a tubular cannula 626 extending along body 462 radially outward from support member 620 and electrode terminals 463. The material for 10 cannula 626 may be advantageously selected from a group of electrically conductive metals so that the cannula 626 functions as both a structural support member for the array of electrode terminals 463 as well as a return electrode 624. The support member 626 is connected to an electrical lead wire (not shown) at its proximal end within a connector housing (not shown) and continues via a suitable connector to power supply 28 to provide 15 electrical continuity between one output pole of high frequency generator 28 and said return electrode 624. The cannula 626 may be selected from the group including stainless steel, copper-based alloys, titanium or its alloys, and nickel-based alloys. The thickness of the cannula 626 is preferably in the range from 0.08 mm to 1.0 mm and more preferably in the range from 0.05 mm to 0.4 mm.

20 As shown in Figs. 11 and 12A, cannula 626 is covered with an electrically insulating sleeve 608 to protect the patient's body from the electric current. Electrically insulating sleeve 608 may be a coating (e.g., nylon) or heat shrinkable plastic (e.g., fluoropolymer or polyester). As shown in Fig. 12A, the proximal portion of the cannula 626 is left exposed to function as the return electrode 624. The length of the return 25 electrode 624,  $L_s$  is preferably in the range from 1 mm to 30 mm and more preferably in the range from 2 mm to 20 mm. The spacing between the most distal portion of the return electrode 624 and the plane of the tissue treatment surface 622 of the electrode support member 620,  $L_1$  is preferably in the range from 0.5 mm to 30 mm and more preferably in the range from 1 mm to 20 mm. The thickness of the electrically insulating sleeve 608 is 30 preferably in the range from 0.01 mm to 0.5 mm and more preferably in the range from 0.02 mm to 0.2 mm.

In the embodiment shown in Fig. 11, the fluid path is formed in catheter by an inner lumen 627 or annular gap between the return electrode 624 and a second tubular

support member 628 within shaft 460. This annular gap may be formed near the perimeter of the shaft 460 as shown in Fig. 11 such that the electrically conducting fluid tends to flow radially inward towards the target site, or it may be formed towards the center of shaft 460 (not shown) so that the fluid flows radially outward. In both of these 5 embodiments, a fluid source (e.g., a bag of fluid elevated above the surgical site or having a pumping device), is coupled to catheter 460 via a fluid supply tube (not shown) that may or may not have a controllable valve.

In an alternative embodiment shown in Fig. 12A, the electrically conducting fluid is delivered from a fluid delivery element (not shown) that is separate from catheter 10 460. In arthroscopic surgery, for example, the body cavity will be flooded with isotonic saline and the catheter 460 will be introduced into this flooded cavity. Electrically conducting fluid will be continually resupplied to maintain the conduction path between return electrode 624 and electrode terminals 463.

The system and method of the present invention is particularly useful in the 15 ablation (i.e., disintegration) of cancer cells and tissue containing cancer cells, such as cancer on the surface of the epidermis, eye, colon, bladder, cervix, uterus and the like. The present invention's ability to completely disintegrate the target tissue can be advantageous in this application because simply vaporizing and fragmenting cancerous tissue (as with prior art devices) may lead to spreading of viable cancer cells (i.e., seeding) 20 to other portions of the patient's body or to the surgical team in close proximity to the target tissue. In addition, the cancerous tissue can be removed to a precise depth while minimizing necrosis of the underlying tissue.

Figs. 13 and 14 illustrate exemplary embodiments of the present invention for (1) distinguishing between cancerous or potentially cancerous (e.g., pre-cancerous) 25 tissue and normal tissue; and (2) volumetrically removing or disintegrating the cancerous tissue into non-viable atoms and molecules. In some cases, the cancerous lesion on the surface of the patient's skin (e.g., skin or colon) is discernable by direct visual (gross) examination or with the aid of magnified visualization (e.g., endoscopic fiber optic camera and associated magnification). In addition, there are other known methods for identifying 30 cancerous lesions on the surface of human tissue. These methods include exposing the suspected tissue site to a topical or an intravenous targeting agent which selectively collects at the site(s) of cancerous tissue. This targeting agent may then be visualized by illumination with: (1) visible light (e.g., in the case of dye-labeled targeting agent); (2)

ultraviolet light in the case of a targeting agent which can be caused to luminesce or becomes "visible" in response to illumination by exposure to ultraviolet (wavelength) light; (3) infrared light in the case of a targeting agent which can be caused to luminesce or becomes "visible" in response to illumination by exposure to infrared (wavelength) light; 5 or (4) other monochromatic or polychromatic light source (e.g., laser light source having one or more wavelengths to perform spectral analysis of the target tissue) to differentiate between normal and cancerous (or pre-cancerous) tissue.

Fig. 13 illustrates an exemplary instrument 700 for distinguishing and removing cancerous tissue. As shown, the instrument 700 generally includes a shaft 702 having a plurality of lumens 704 extending therethrough for the passage of other instruments. In this embodiment, an electrosurgical probe 706 extends through one of the lumens 704. Probe 706 may have a similar construction as the probes and catheters described above, including one or more electrode terminals 708 for ablation or disintegration of cancerous tissue 710, as described in detail above. A targeting agent 712 10 has already been applied to the cancerous tissue 710, and an illumination source 714 (e.g., ultraviolet light) extends through another lumen 704 in instrument 700 for visualizing the targeting agent 712. In one embodiment, the instrument 700 may also include a second illumination source 716, such as a fiber-optic visible light source, for viewing probe 706. 15

Another approach for distinguishing between normal and cancerous (or pre-cancerous) lesions on the surface of human tissue is to illuminate the suspected tissue site with monochromatic, polychromatic or a series of monochromatic wavelengths to perform a spectral analysis of the reflected/scattered light. This approach would not necessarily require the use of a targeting agent which preferentially concentrates at the sites containing cancerous tissue. Rather, this approach relies on the differences in the spectral response 20 of normal and cancerous tissue to the selected wavelength(s) used to illuminate the tissue. 25

Fig. 14 illustrates another embodiment according to the present invention for distinguishing and removing (disintegrating) cancerous tissue. As shown, an electrosurgical probe 800 includes an array of electrically isolated electrode terminals 802 supported by an insulating matrix 804, as described above. In this embodiment, one or 30 more electrical properties of the tissue are measured by the electrode terminals 802 to distinguish cancerous tissue from normal tissue. These measured electrical properties may include electrical conductivity at one, several or a range of frequencies (e.g., in the range from 1 kHz to 100 MHZ, dielectric constant, capacitance of combinations of the above. In

this embodiment, an audible signal may be produced when the sensing electrode(s) at the tip of probe 800 detect cancerous or pre-cancerous tissue. Alternatively, direct feedback control can be provided to only supply power to the ablating electrodes, either individually or to the complete array of electrodes, if and when the tissue encountered at the working 5 end of the probe is cancerous or pre-cancerous based on the measured electrical property or properties of tissue.

Other modifications and variations can be made to disclose embodiments without departing from the subject invention as defined in the following claims. For example, it should be noted that the invention is not limited to an electrode array 10 comprising a plurality of electrode terminals. The invention could utilize a plurality of return electrodes, e.g., in a bipolar array or the like. In addition, depending on other conditions, such as the peak-to-peak voltage, electrode diameter, etc., a single electrode terminal may be sufficient to contract collagen tissue, ablate tissue, or the like.

**WHAT IS CLAIMED IS:**

1. A method for removing tissue cells comprising:  
positioning an electrode terminal in close proximity to a body structure  
5 containing tissue cells; and  
applying a sufficient high frequency voltage difference between the electrode terminal and a return electrode to volumetrically remove at least a portion of the tissue cells through the disintegration of organic molecules into non-viable atoms and molecules.
- 10 2. The method of claim 1 wherein the non-viable atoms and molecules are in the form of non-condensable gases.
- 15 3. The method of claim 2 wherein the non-condensable gases comprises at least one of hydrogen, oxides of carbon, oxygen and nitrogen compounds.
4. The method of claim 1 wherein the tissue cells are cancer cells.
- 20 5. The method of claim 4 further comprising distinguishing between the cancer cells and non-cancerous tissue adjacent to the cancer cells prior to the applying step.
6. The method of claim 5 wherein the distinguishing step comprises detecting electrical properties of the tissue cells adjacent to the electrode terminal.
- 25 7. The method of claim 6 wherein the electrical properties comprise electrical conductivity, dielectric constant, capacitance or combinations thereof.
- 30 8. The method of claim 1 further comprising an electrode array including a plurality of electrically isolated electrode terminals.
9. The method of claim 1 wherein the electrode terminal comprises a single electrode at or near a distal end of an electrosurgical instrument.

10. The method of claim 1 further comprising applying a high frequency voltage difference between the electrode terminal and a return electrode located on an external surface of the patient's body.

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11. The method of claim 1 wherein the return electrode and the electrode terminal are both located on an electrosurgical instrument.

10 12. The method of claim 1 further comprising positioning the electrode terminal within electrically conductive fluid.

13. The method of claim 12 further comprising delivering the electrically conductive fluid to the electrode terminal to substantially surround the electrode terminal with the electrically conductive fluid.

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14. The method of claim 12 further comprising positioning the electrode terminal and the return electrode within electrically conductive fluid to generate a current flow path between the return electrode and the electrode terminal.

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15. The method of claim 8 further comprising independently controlling current flow from at least two of the electrode terminals based on impedance between the electrode terminal and a return electrode.

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16. The method of claim 12 further comprising applying sufficient voltage to the electrode terminal in the presence of the electrically conducting fluid to vaporize at least a portion of the fluid between the electrode terminal and the tissue structure.

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17. The method of claim 16 further comprising accelerating charged particles from the vaporized fluid to the tissue structure to cause dissociation of the molecular bonds within the tissue structure.

18. A method for removing cancerous tissue comprising:

positioning an electrode terminal in contact with or in close proximity to a body structure containing cancerous tissue; and

applying a sufficient high frequency voltage to the electrode terminal to convert at least a portion of the cancerous tissue into non-viable atoms and molecules.

5

19. A system for applying electrical energy to tissue comprising:  
an electrosurgical probe having a shaft with a proximal end portion, a distal end portion and an electrode terminal at or near the distal end portion;

a return electrode;

10 a high frequency power supply coupled to the probe for applying a high frequency voltage difference between the electrode terminal and the return electrode; and  
wherein the high frequency voltage difference is sufficient to volumetrically remove tissue cells adjacent to or in contact with the electrode terminal through the disintegration of organic molecules into non-viable atoms and molecules.

15

20. The system of claim 19 wherein the non-viable atoms and molecules are in the form of non-condensable gases.

21. The system of claim 19 wherein the non-condensable gases comprises at least one of hydrogen, oxides of carbon, oxygen and nitrogen compounds.

22. The system of claim 19 wherein the tissue cells are cancer cells.

23. The system of claim 22 further comprising a detection element coupled to the electrode terminal for distinguishing between the cancer cells and non-cancerous tissue adjacent to the cancer cells.

24. The system of claim 23 wherein the detection element detects electrical properties of the tissue cells adjacent to the electrode terminal.

30

25. The system of claim 24 wherein the electrical properties comprise electrical conductivity, dielectric constant, capacitance or combinations thereof.

26. The system of claim 19 further comprising a fluid delivery element defining a fluid path in electrical contact with the return electrode and the electrode terminal to generate a current flow path between the return electrode and the electrode terminal.

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27. The system of claim 19 wherein the return electrode forms a portion of the shaft.

10 28. The system of claim 19 further including an insulating member positioned between the return electrode and the electrode terminal, the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and a body structure at the target site when the electrode terminal is positioned in close proximity or in partial contact with the body structure.

15 29. The system of claim 19 wherein the electrode terminal comprises an electrode array disposed near the distal end of the shaft, the array including a plurality of electrically isolated electrode terminals disposed over a contact surface.

20 30. The system of claim 19 wherein the electrode terminal comprises a single active electrode disposed near the distal end of the shaft.

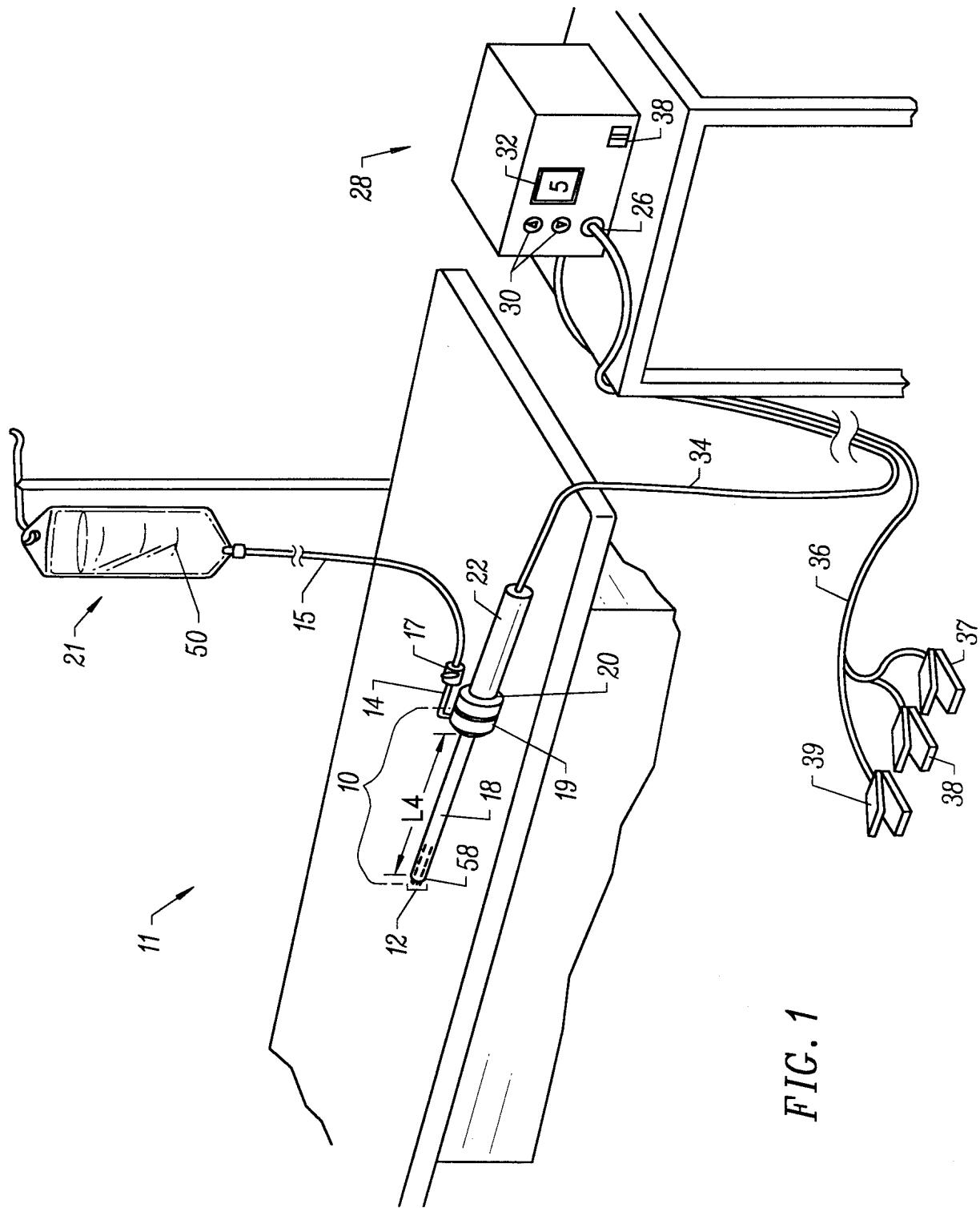
31. The system of claim 29 further comprising a plurality of power limiting elements each coupled to one of the electrode terminals for independently controlling current flow to each of the electrode based on impedance.

25

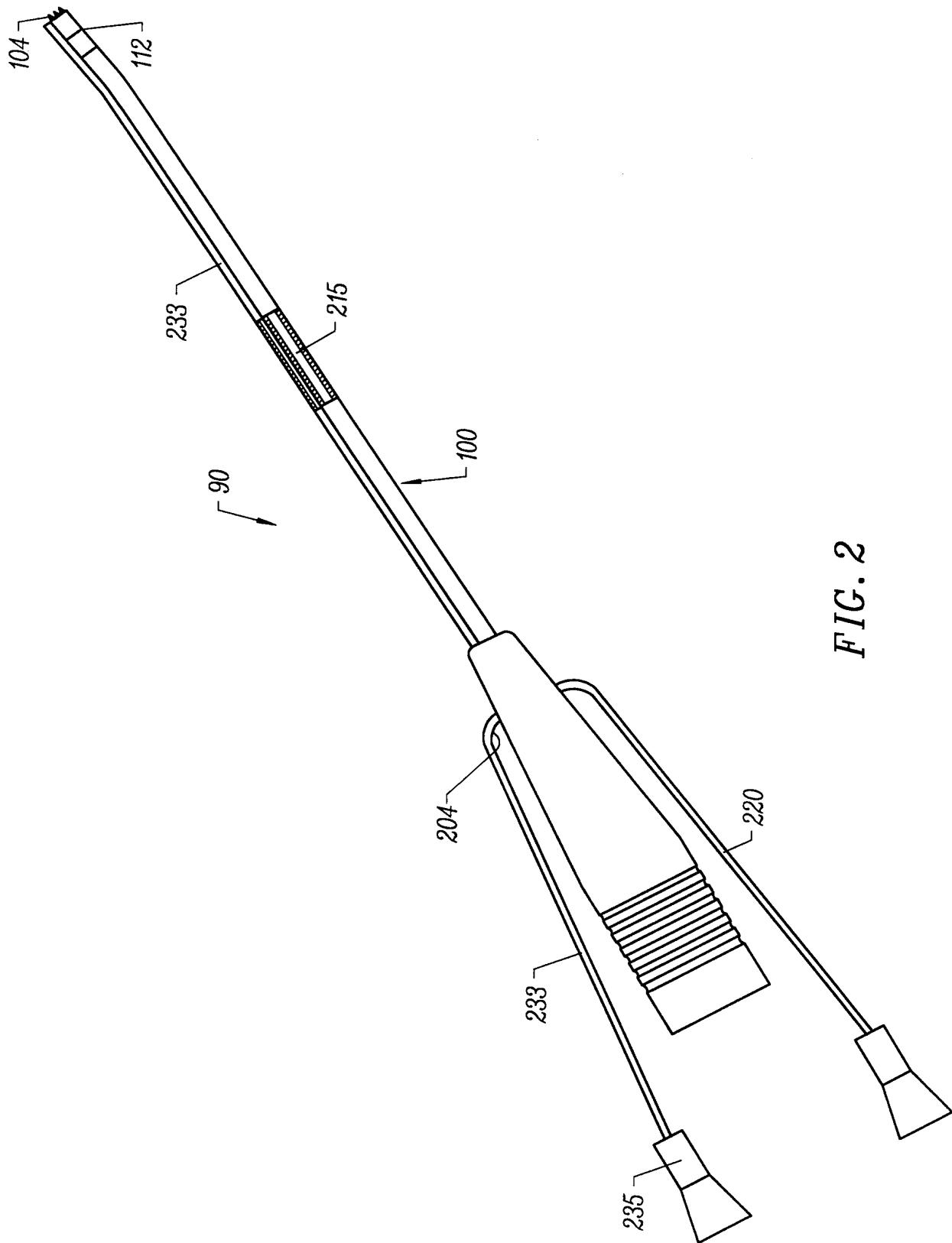
32. The system of claim 19 further comprising a fluid aspiration element for aspirating fluid and products of ablation including the non-viable atoms and molecules from the target site.

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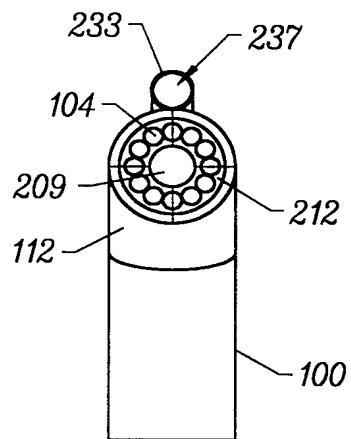


FIG. 3

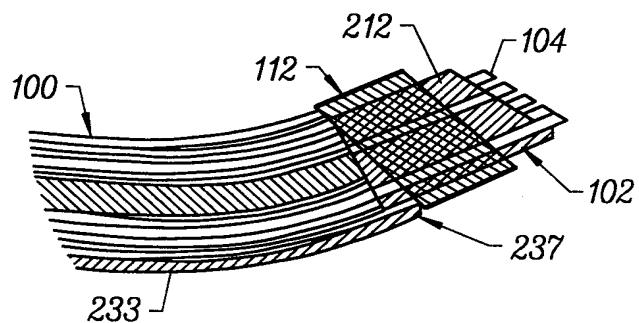


FIG. 4

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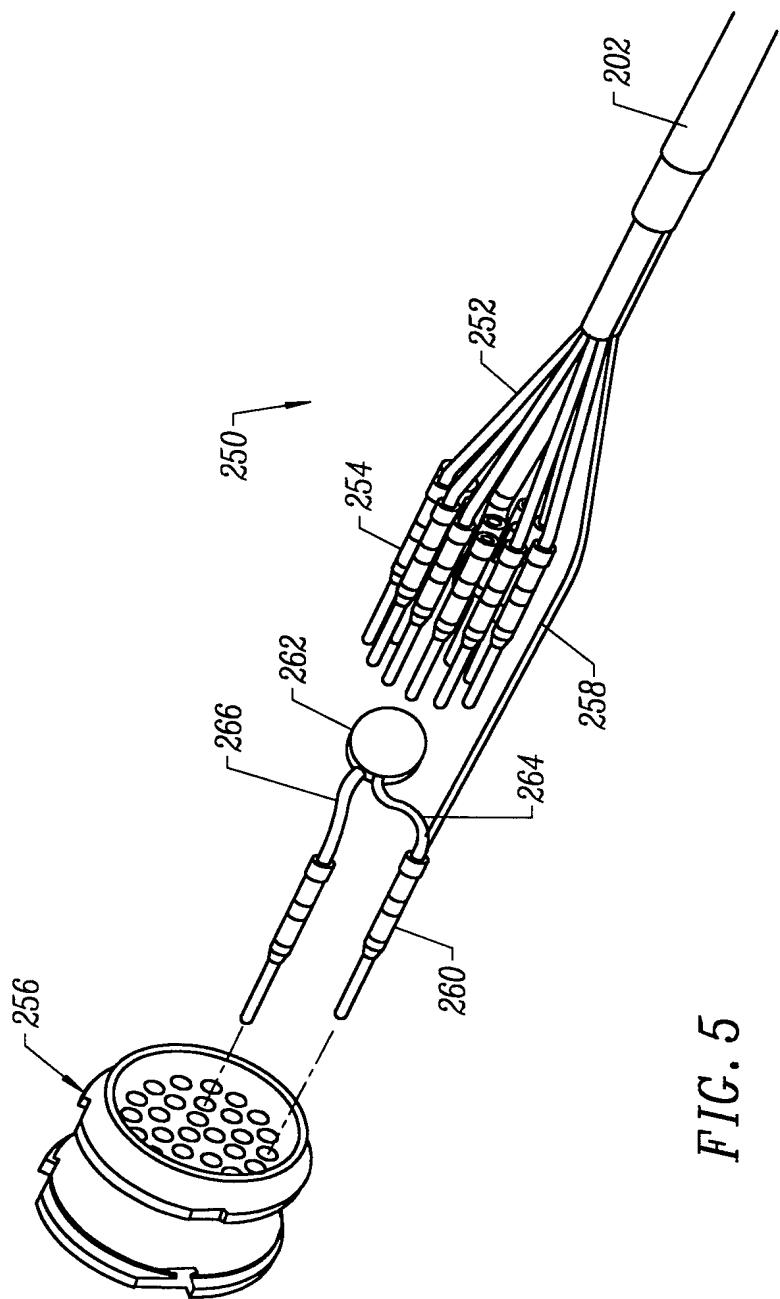


FIG. 5

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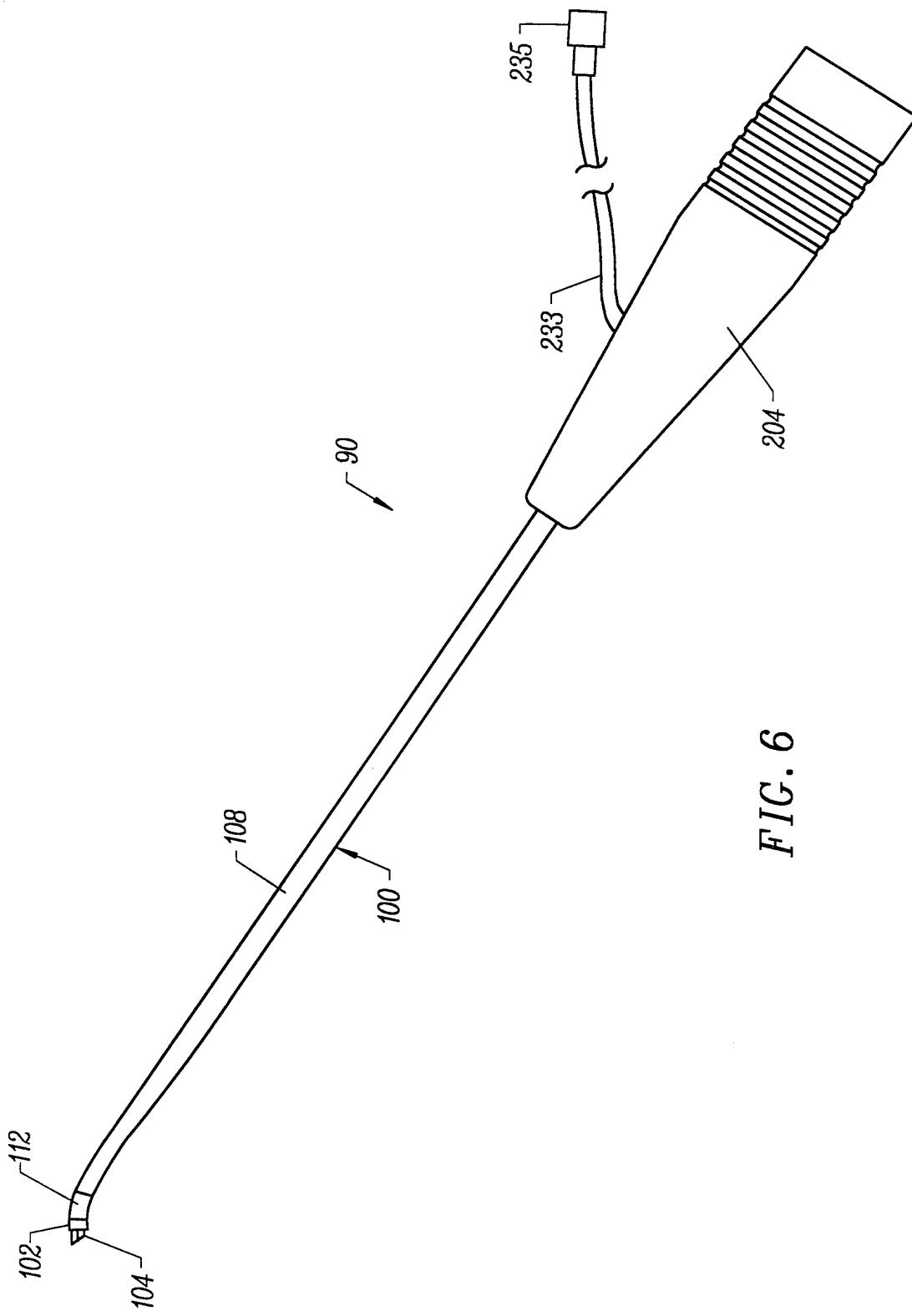


FIG. 6

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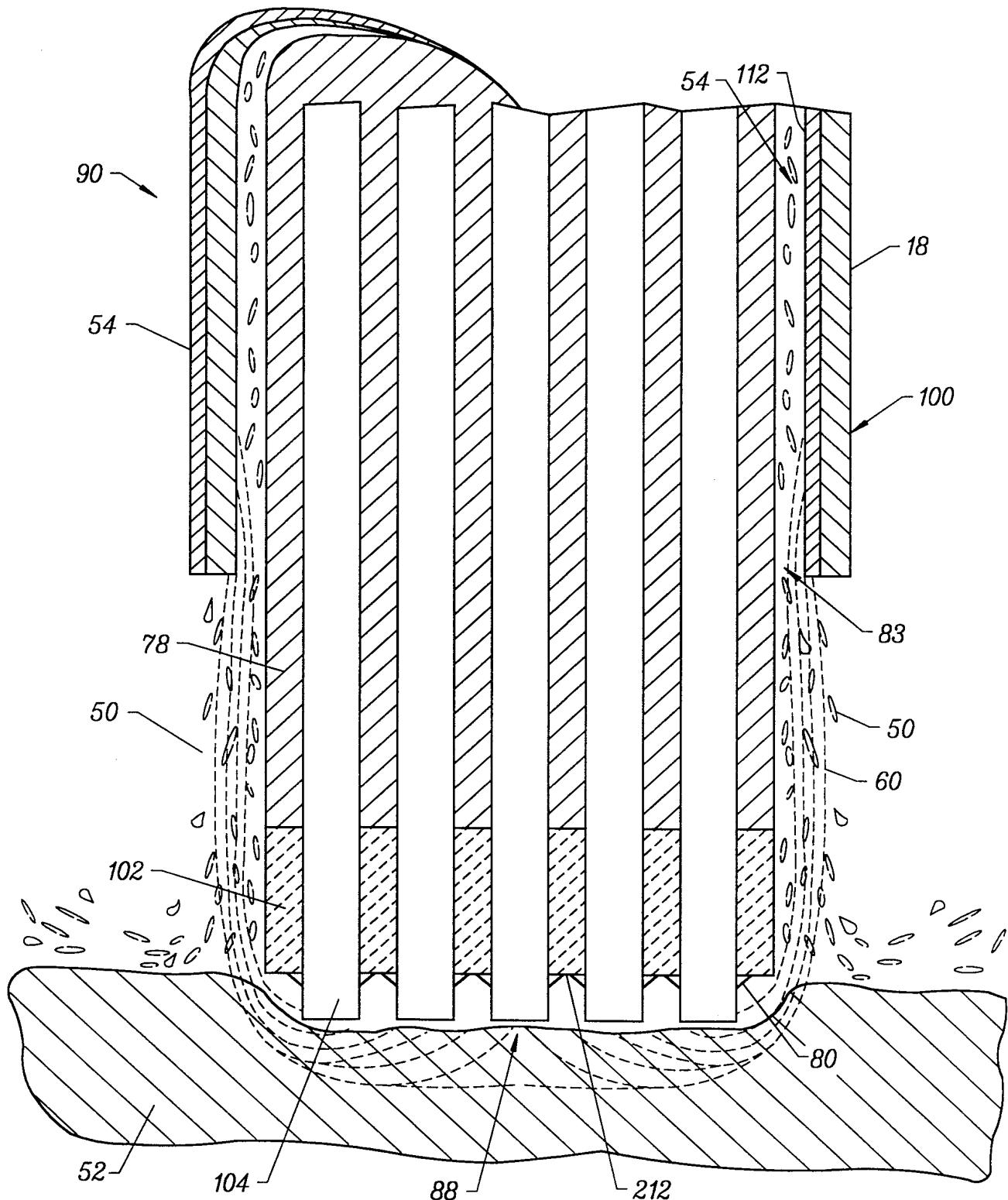


FIG. 7A

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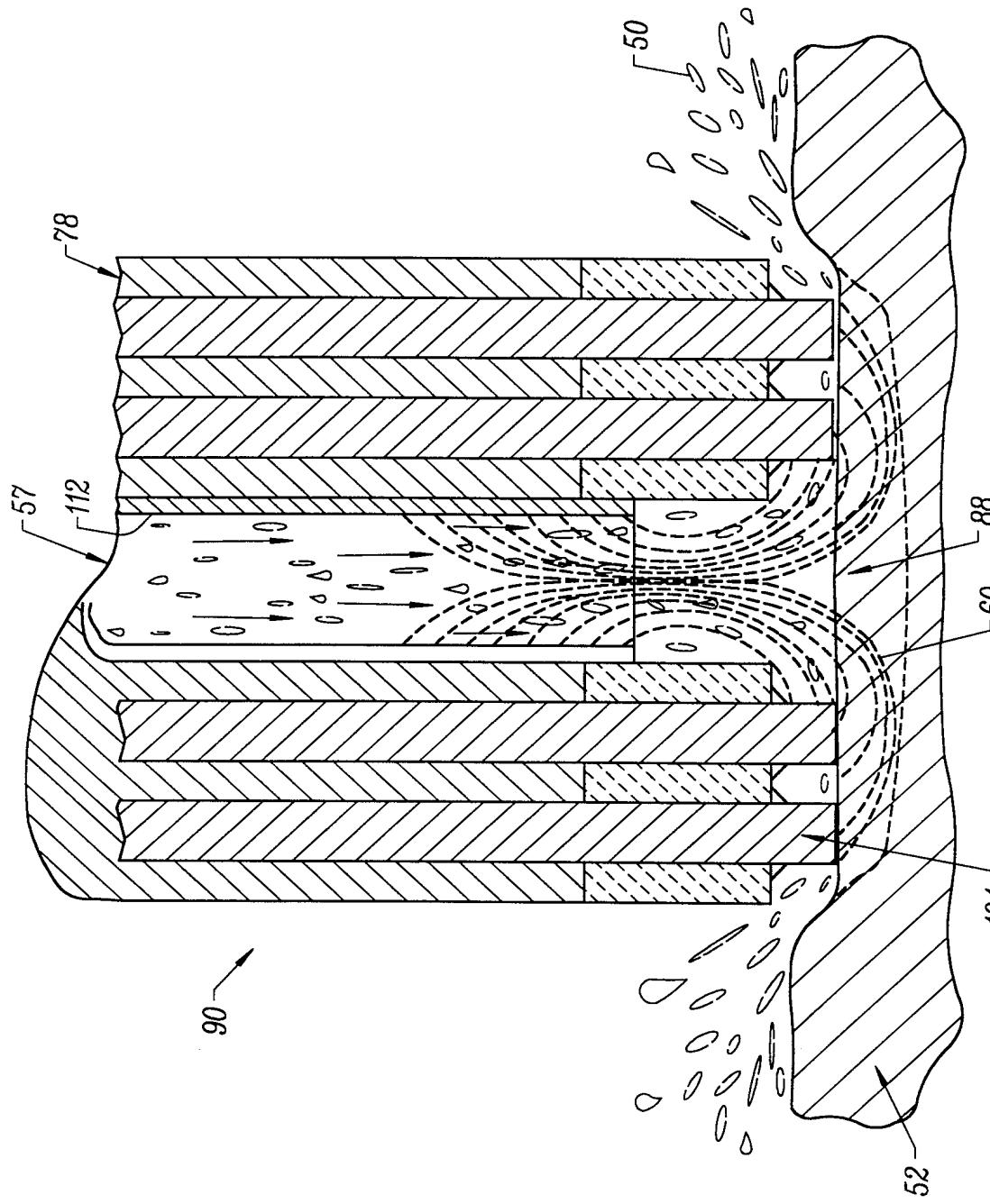


FIG. 7B

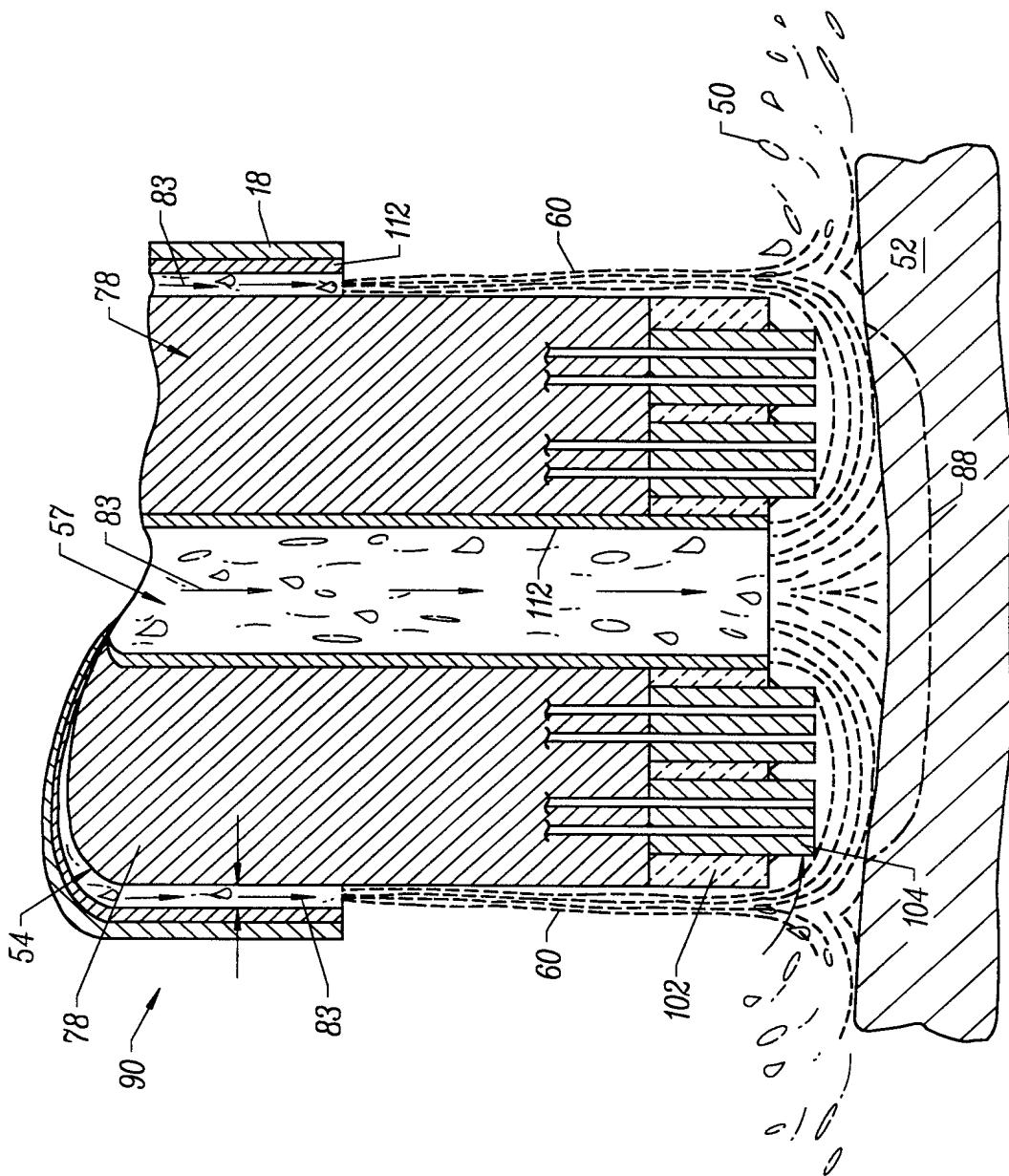


FIG. 7C

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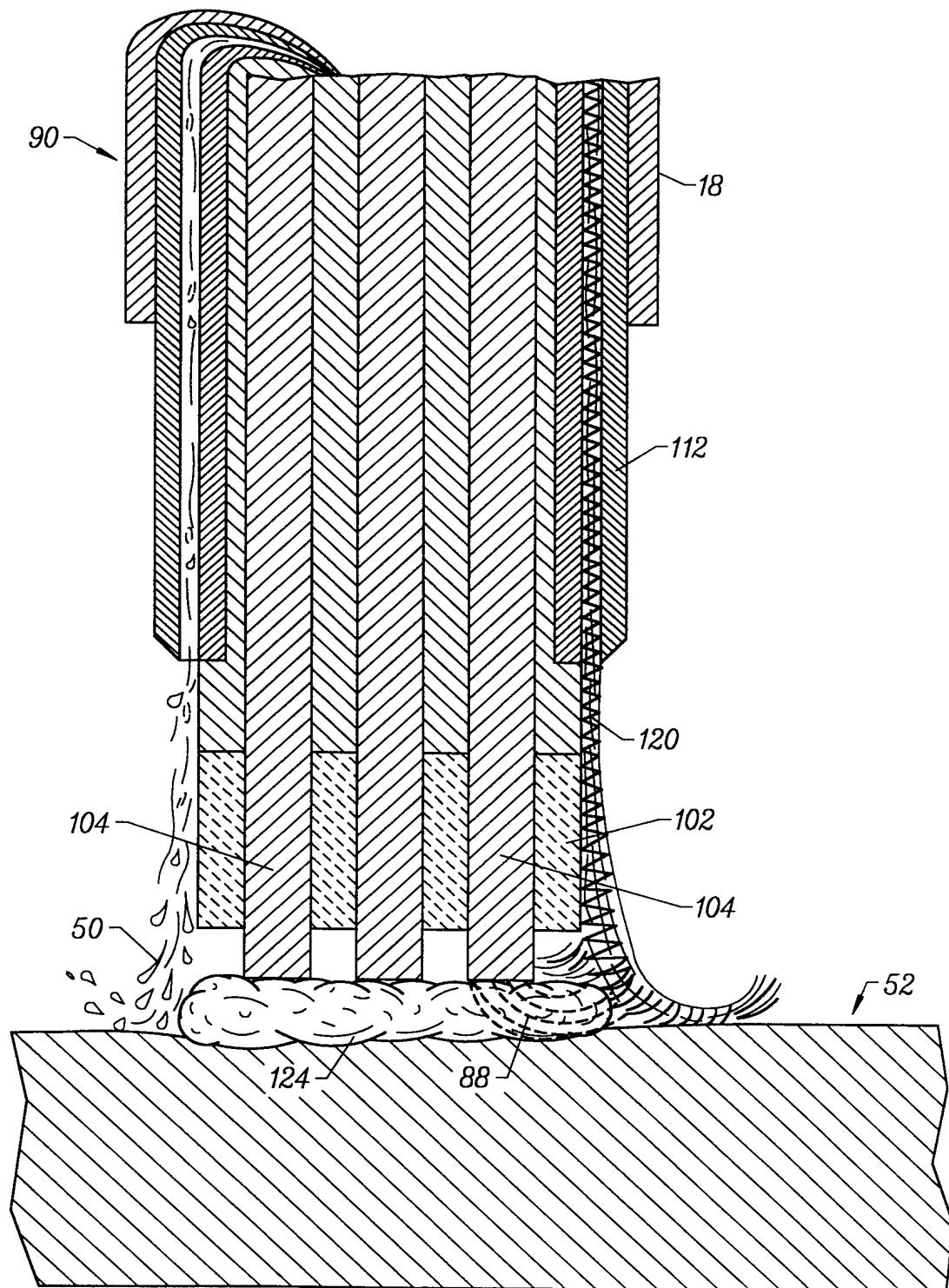
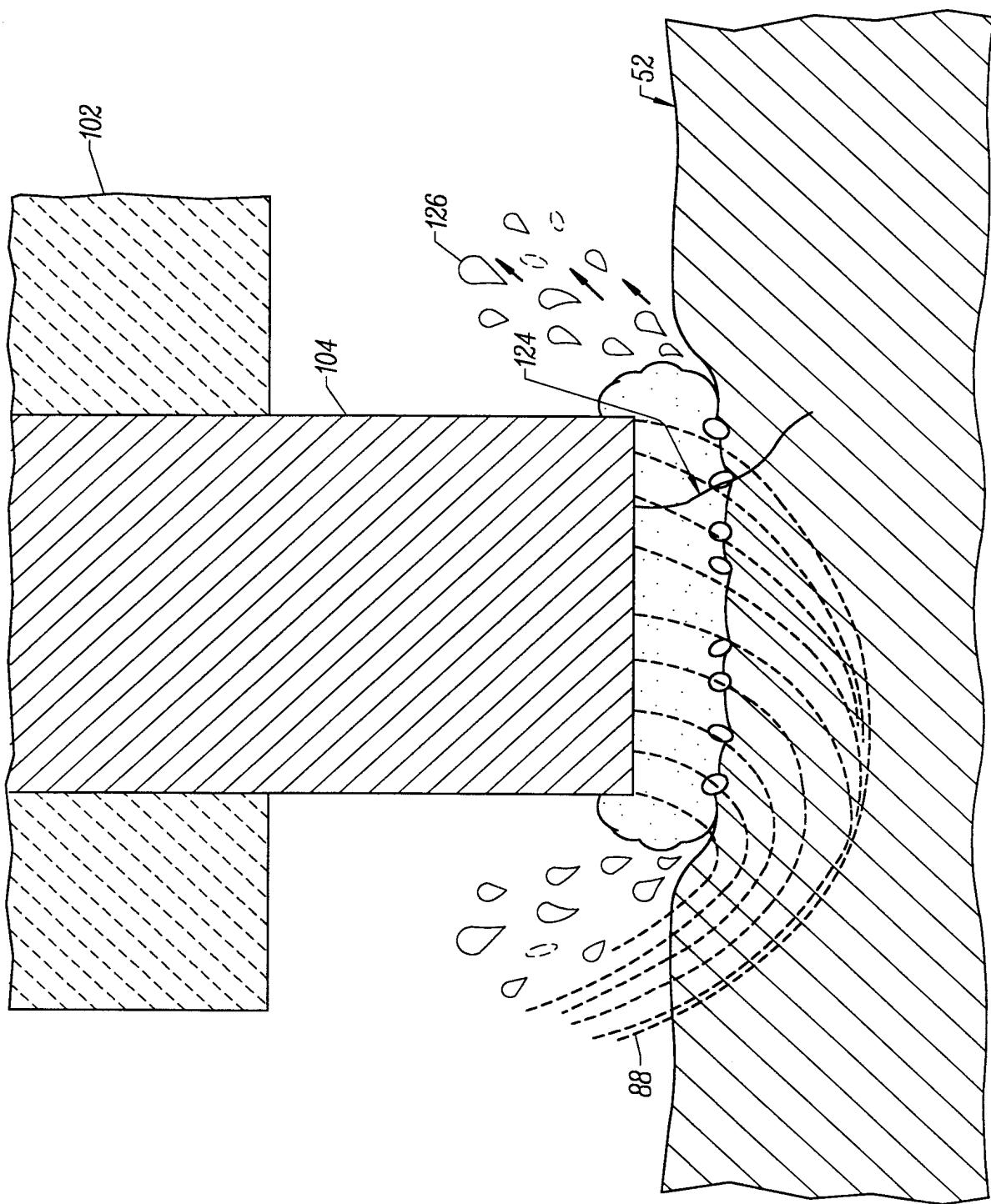
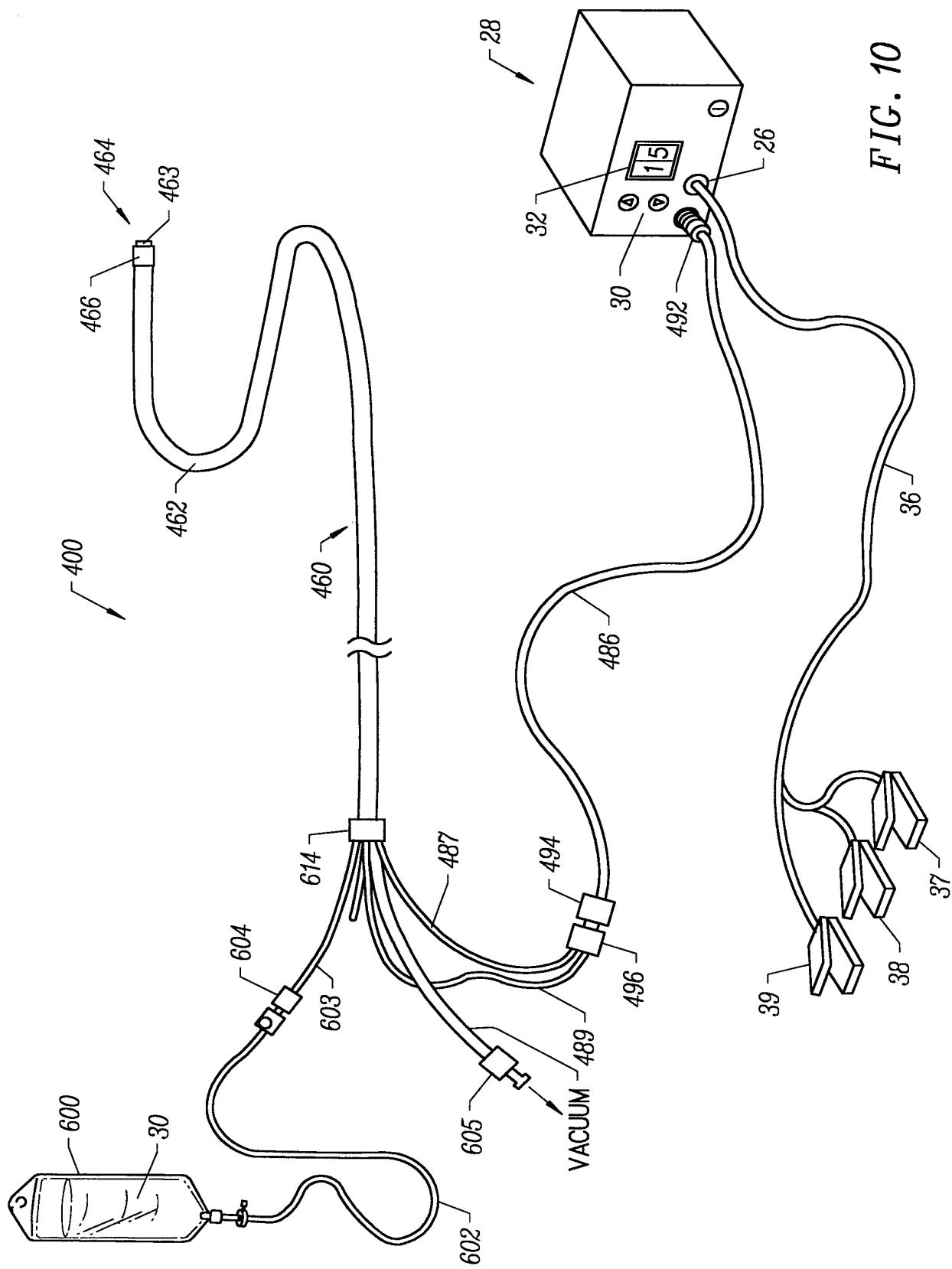


FIG. 8

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SUBSTITUTE SHEET (RULE 26)

FIG. 10

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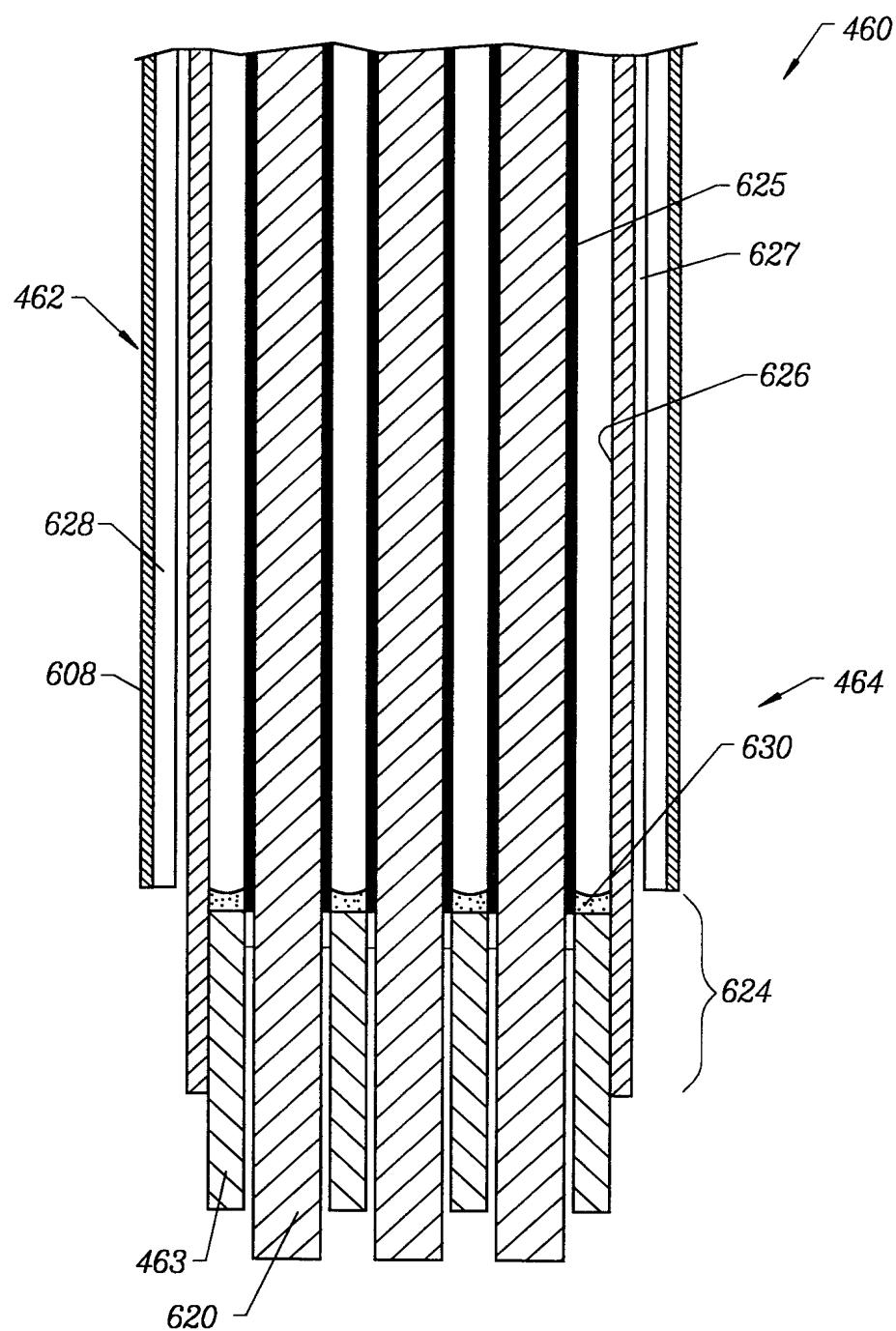


FIG. 11

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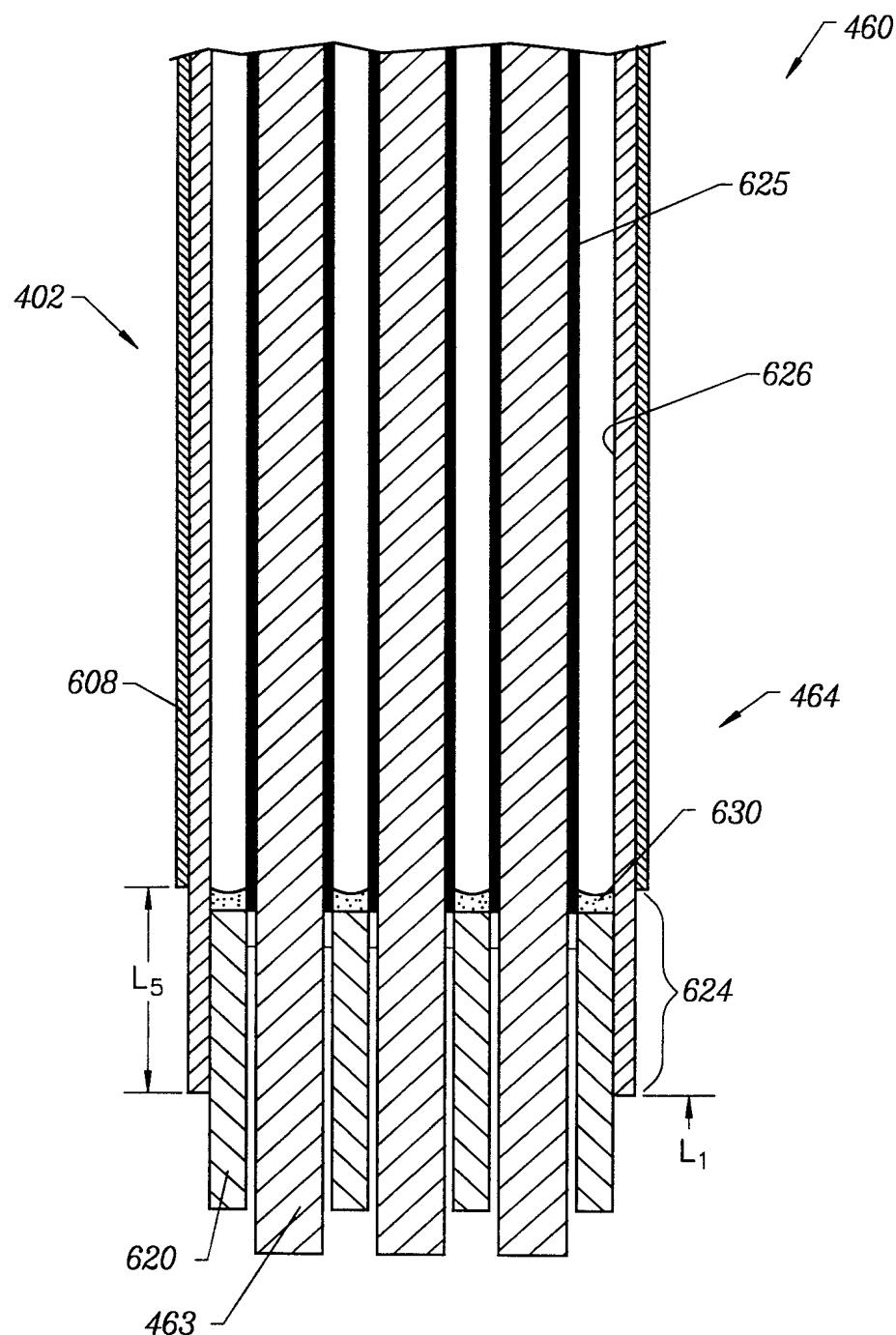


FIG. 12A

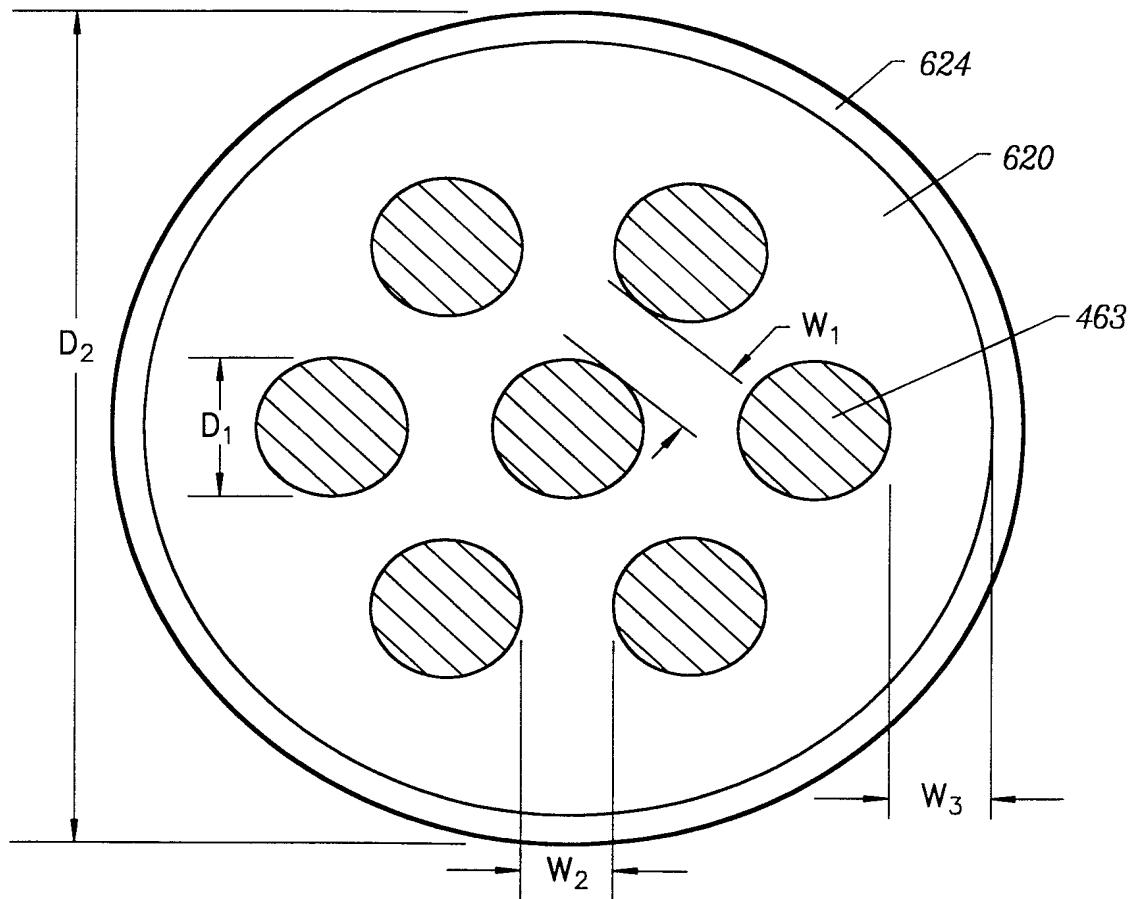


FIG. 12B

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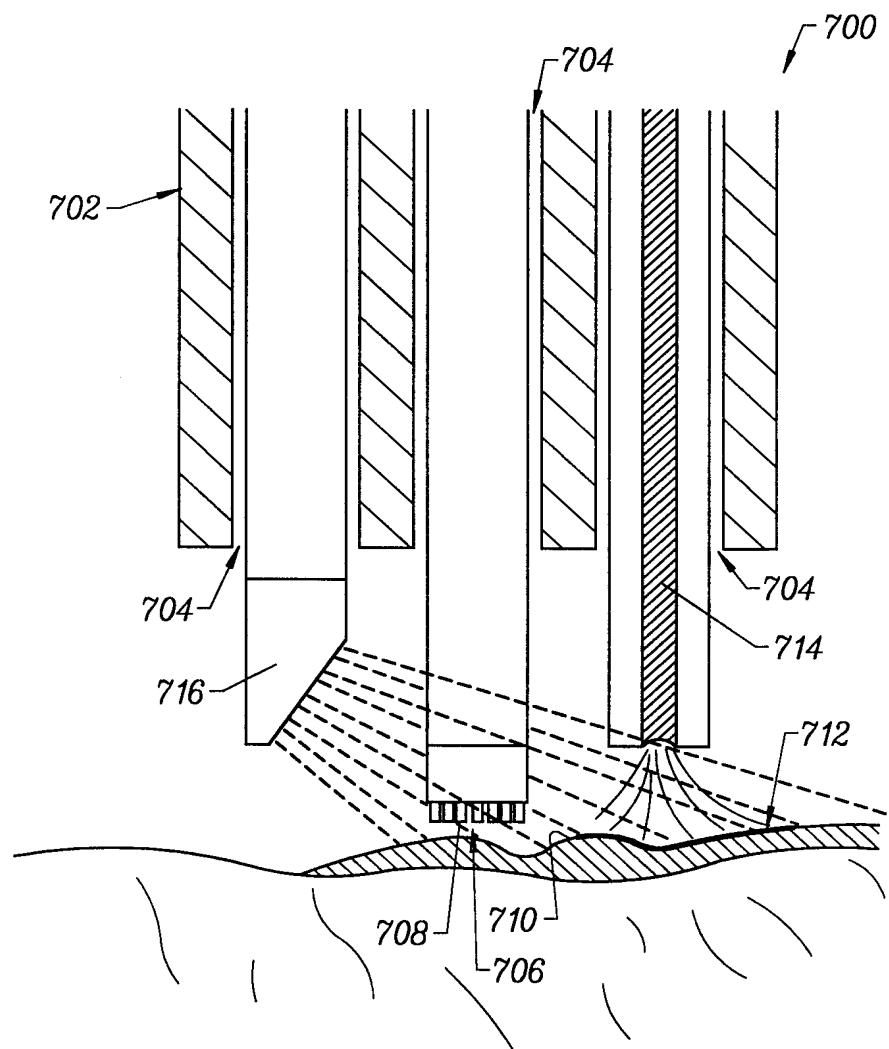


FIG. 13

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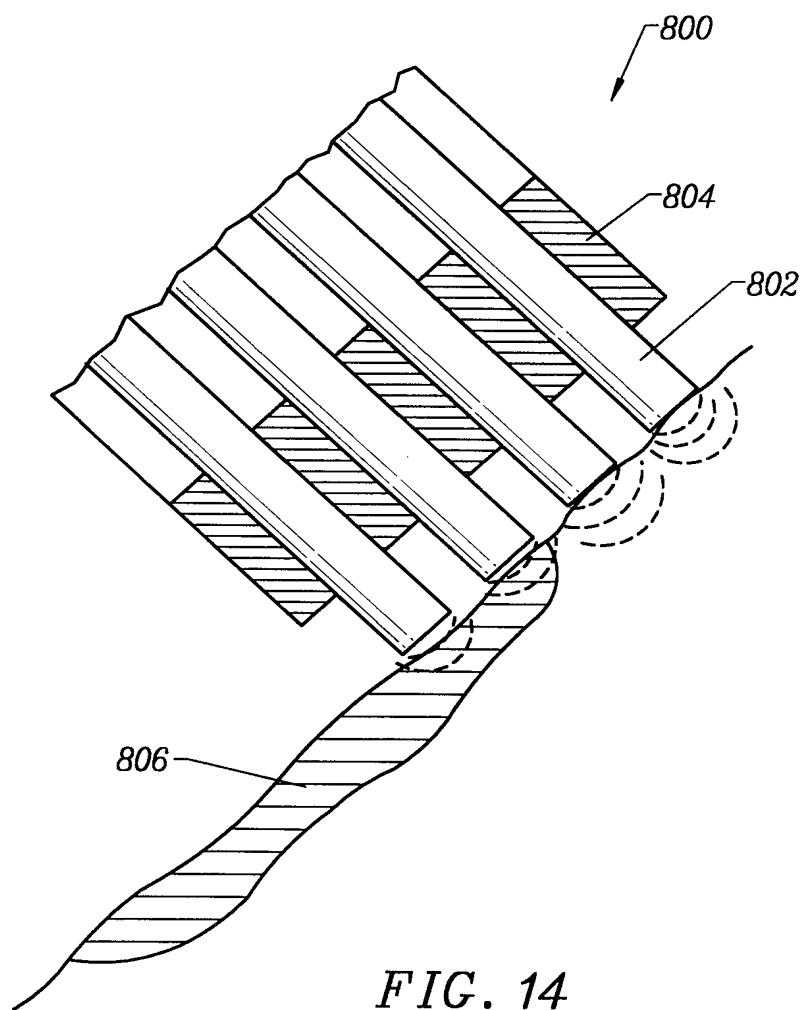


FIG. 14

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US99/14685

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/36

US CL :606/41

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/898; 604/21, 22, 114; 606/27-31, 41, 42, 45-50; 607/100-105

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,683,366 A (EGGERS et al) 04 November 1997, whole document.	1-32
X	US 5,658,278 A (IMRAN et al), 19 August 1997, whole document	1-3, 8-17, 19-32
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Y		4-7, 18
X	US 5,569,242 A (LAX et al) 29 October 1996, whole document.	1-3, 8-17, 19-32
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Y		4-7, 18
X	US 5,370,675 A (EDWARDS et al) 06 December 1994, whole document.	1-32

Further documents are listed in the continuation of Box C.  See patent family annex.

• Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

26 AUGUST 1999

Date of mailing of the international search report

21 OCT 1999

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